



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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**OFFICE OF PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES**

MEMORANDUM

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Attached is HED's human-health risk assessment scoping document for glyphosate to support Registration Review.

Executive Summary

Glyphosate is a non-selective herbicide which acts via blocking the activity of the enzyme, 5-enolpyruvylshikimate 3-phosphate synthase (EPSPS). EPSPS is produced only by green plants and is involved in the synthesis of the amino acids tyrosine, tryptophan, and phenylalanine. Glyphosate is registered for use on a variety of fruit, vegetable, and field crops as well as for aquatic and terrestrial uses. Glyphosate is also registered for use on transgenic crop varieties such as canola, corn, cotton, soybeans, sugar beets, and wheat. The most recent human-health risk assessment for glyphosate was completed in 2006 (Memo, J. Tomerlin, 29-Sep-06, D321992). Since that risk assessment, HED has reviewed petitions for application of glyphosate to certain transgenic crops and concluded that revisions to the 29-Sep-2006 risk assessment were unnecessary at the time of review.

Glyphosate is of low acute toxicity following oral, dermal, and inhalation exposure. An acute dose and endpoint have not been selected for any population subgroups because no effects that could be attributed to a single exposure (dose) were observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Glyphosate has been classified as a “Group E” chemical (evidence of non-carcinogenicity for humans), based upon lack of convincing evidence of carcinogenicity in adequate studies in two animal species (mice and rats). No significant reproductive or developmental toxic effects were found in toxicity studies in the rat and rabbit. Neurotoxicity has not been observed in any of the acute, subchronic, chronic, developmental, or reproductive studies performed with glyphosate. However, new data requirements which include the requirement of an acute neurotoxicity study and a subchronic neurotoxicity study, as well as an immunotoxicity study, have been established under 40 CFR Part 158 for registration of pesticides for food and non-food uses.

Aminomethylphosphonic acid (AMPA) is a metabolite of glyphosate. In 1992, the HED Metabolism Committee determined that, based on toxicological considerations, AMPA need not be regulated, and in 1994, it was determined that, based on toxicological considerations, AMPA need not be regulated regardless of levels observed in foods or feeds. *N*-acetyl-glyphosate is a metabolite of glyphosate which is formed in certain transgenic crops and is considered to be equally toxic as glyphosate (Memo, T. Bloem, 18-Mar-08, D345923). *N*-acetyl-AMPA was detected as one of the metabolites formed in these crops and was excluded as a residue of concern based on residue and toxicity considerations (Memo, T. Bloem, 18-Mar-08, D345923). The decision that AMPA and *N*-acetyl-AMPA need not be regulated, regardless of levels observed in foods or feeds, may be revisited during the registration review process.

The dietary-exposure database is adequate to support the existing registrations. An acute dietary-exposure assessment was not required because no acute toxicological endpoint has been determined for glyphosate. The 2006 chronic dietary-exposure assessment for glyphosate was conducted using the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM™-FCID, ver. 2.03), and incorporated tolerance-level residues, 100% crop treated data for all commodities, and worst-case scenario drinking water exposure estimates. The residue chemistry database is sufficient to support the current registrations; however, there are some outstanding studies for some of these registrations which, if submitted, would change the registration status from conditional to unconditional.

A new residential exposure risk assessment is required due to the registration of a new residential-use product with an application rate which is higher than the rate previously assessed. A new aggregate risk assessment will need to be conducted once the residential exposure risk assessment has been completed. The increase in the residential application rate is not expected to lead to residential exposures which exceed HED's level of concern (margins of exposure (MOEs)<100) or affect the aggregate risk in such a way that it exceeds HED's level of concern. No occupational handler or occupational post-application assessments were required because no short-term dermal or inhalation toxicity endpoints were identified by HED.

The U.S., Mexico, and Codex residue definitions are harmonized. There are discrepancies between the Canadian residue definition and residue definitions of the U.S., Mexico, and Codex. For some raw agricultural and livestock commodities, the tolerance and Maximum Residue Limits (MRLs) for the U.S., Canada, Mexico, and Codex are harmonized; however there are a variety of tolerances and MRLs for commodities which are not harmonized.

Introduction

HED has evaluated the status of the human-health assessments for glyphosate to determine if sufficient data are available and if any updates are required to support Registration Review. HED has considered the most recent human-health risk assessment for glyphosate (Memo, J. Tomerlin, 29-Sep-06, D321992); the most recent human-health risk assessment for glyphosate applied to transgenic crops (Memo, T. Bloem, 18-Mar-08, D345923); updates to its toxicity, exposure, and usage databases; and the most updated Agency science policy and risk assessment methodologies to determine the scope of work necessary to support Registration Review. In addition, HED conducted an open search to look for new literature relevant to the human-health risk assessment.

Glyphosate is a non-selective herbicide registered for use on a variety of fruit, vegetable, and field crops. Registered uses range from tree nuts, citrus, and grapes to corn, soybeans, cotton, and rice. Glyphosate is also registered for use on transgenic crop varieties such as canola, corn, cotton, soybeans, sugar beets, and wheat. Aquatic and terrestrial registered uses of glyphosate include non-selective control of nuisance aquatic weeds, ornamentals, greenhouses, residential areas, ornamental lawns and turf, fallow land, pastures, and nonagricultural rights-of-way. Glyphosate is formulated in liquid and solid forms, and it is applied using ground and aerial equipment. Application rates of glyphosate to food crops range from <1 pound (lb) of acid equivalent (ae) per acre (A) for a variety of crops to approximately 15 lb ae/A for spray and spot treatments of crops including tree nuts, apples, citrus, and peaches. Residential lawn and turf application rates range from <1 lb ae/A to approximately 10.5 lb ae/A.

The application timing of glyphosate is varied. Glyphosate can be applied early and late in the season, at pre-plant, planting, pre-emergence, pre-bloom, bud stage, pre-transplant, pre-harvest, post-plant, post-transplant, post-bloom, and post-harvest. It can also be applied during dormant stages and to fallow land, established plantings, stubble, and when needed.

Since the glyphosate RED (Reregistration Eligibility Decision) was completed in 1993, the following commodities have been assessed and registered: Aloe vera; Ambarella; Artichoke, globe; Bamboo, shoots; Betelnut; Biriba; Blimbe; Borage, seed; Cacao bean; Cactus, fruit; Cactus, pads; Canola, meal; Canola, seed; Cattle, kidney; Cattle, liver; Chaya; Crambe, seed; Custard apple; Dokudami; Durian; Egg; Epazote; Feijoa; Flax, meal; Flax, seed; Galangal, roots; Ginger, white, flower; Gourd, buffalo, seed; Governor's plum; Gow kee, leaves; Herbs subgroup 19A; Hop, dried cones; Ilama; Imbe; Imbu; Kava roots; Kenaf, forage; Lesquerella, seed; Leucaena, forage; Mangosteen; Meadowfoam, seed; Mioga, flower; Mustard, seed; Noni; Nut, pine; Okra; Oregano, Mexican, leaves; Palm heart; Palm heart, leaves; Papaya, mountain; Pawpaw; Pepper leaf, fresh leaves; Perilla, tops; Pulasan; Quinoa, grain; Rambutan; Rose apple; Safflower; Salal; Sapote, mamey; Sesame, seed; Spanish lime; Spice subgroup 19B; Star apple; Starfruit; Stevia, dried leaves; Strawberry; Surinam cherry; Teff, grain; Ti, leaves; Ti, roots; Ugli fruit; Wasabi, roots; Water spinach, tops; Watercress, upland; Wax jambu; and Yacon, tuber.

The qualitative nature of glyphosate residues in plants and livestock is adequately understood. The terminal residue to be regulated in nontransgenic plants and transgenic corn and canola modified to express the *Agrobacterium* sp. EPSPS and oxireductase genes is glyphosate *per se*. For crops (currently soybeans and corn) which have a transgenic variety that has been engineered to express the microbial glyphosate acetyltransferase gene (*gat4601*), the combined residues to be regulated are glyphosate and *N*-acetyl-glyphosate. The residue chemistry database is sufficient to support the current registrations; however, there are some outstanding studies which, if submitted, would change the registration status from conditional to unconditional.

Data needs and risk assessment updates required under registration review for glyphosate are as follows:

- An immunotoxicity study, acute neurotoxicity study, and a subchronic neurotoxicity are required as specified in the new 40 CFR Part 158 data requirements.
- Two toxicology studies (MRIDs 47311001 and 47311004) have been submitted which are still in the process of being reviewed. Once the reviews are complete, the reviews need to be added to the Integrated Hazard Assessment Database (IHAD).
- Nature of the residue studies in plants and livestock and ruminant and poultry feeding studies which were requested in recent HED Memos (Memo, T. Bloem, 18-Mar-08, D345923; and Memo, T. Bloem, 29-Oct-08, D357880) are still required.
- A new residential exposure risk assessment is required due to the registration of a new residential-use product with an application rate which is higher than the rate previously assessed.
- A new aggregate risk assessment is required once the residential exposure risk assessment has been completed.

Hazard Identification/Toxicology

Glyphosate

Glyphosate is a non-selective herbicide which acts via blocking the activity of EPSPS. EPSPS is produced only by green plants and is involved in the synthesis of the amino acids tyrosine, tryptophan, and phenylalanine.

Glyphosate is of low acute toxicity following oral, dermal, and inhalation exposure, since all studies are in Toxicity Category III or IV. It is a mild eye irritant (Toxicity Category III), slight skin irritant (Toxicity Category IV), and is not a dermal sensitizer in guinea pigs. Inhalation risk assessments (any time period) are not required based on the low toxicity of the formulation products (Toxicity Category III or IV) and the physical characteristics of the technical product (wet cake). An acute dose and endpoint have not been selected for any population subgroups because no effects that could be attributed to a single exposure (dose) were observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Therefore, a dose and endpoint were not identified for acute dietary risk assessment.

A chronic feeding/carcinogenicity study in rats found no systemic effects in any of the parameters examined (body weight, food consumption, clinical signs, mortality, clinical pathology, organ weights, and histopathology). In a second chronic feeding/carcinogenicity study in rats tested at higher dietary levels, a lowest-observed-adverse-effect level (LOAEL) was identified at 20,000 parts per million (ppm; approximately 940 mg/kg/day) based on decreased body weight gains in the females and increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased absolute liver weight, and increased relative liver weight/brain weight in males. No evidence of carcinogenicity was found in rats. There was also no evidence of carcinogenicity in mice. In a chronic toxicity study in dogs, no systemic effects were found in all examined parameters.

On 26-Jun-1991, the HED Carcinogenicity Peer Review Committee (CPRC) evaluated the weight of the evidence on glyphosate with particular emphasis on its carcinogenic potential. The Committee concluded that glyphosate should be classified as a “Group E” chemical (evidence of non-carcinogenicity for humans), based upon lack of convincing carcinogenicity evidence in adequate studies in two animal species (mice and rats).

Acceptable developmental toxicity studies in the rat and rabbit are available, as is an acceptable 2-generation reproduction study in the rat. No significant reproductive and developmental toxic effects were found. A focal tubular dilation of the kidneys was observed in a three-generation reproductive study on rats at the 30-mg/kg/day level [highest dose tested (HDT)], however a two-generational reproductive study on rats did not observe the same effect at the 1500-mg/kg/day level (HDT), nor were any adverse reproductive effects observed at any dose level. In 1991, the HED Reference Dose (RfD) Committee concluded that the focal tubular dilation of the kidneys at the 30-mg/kg/day level was a spurious rather than a glyphosate-related effect.

In a prenatal developmental toxicity study in rats, maternal (systemic) effects observed included mortality, increased clinical signs, and reduced body-weight gain at the HDT (3500 mg/kg/day). Developmental (fetal) effects were observed only in the high-dose group and included decreases

in total implantations/dam and nonviable fetuses/dam, increased number of litters and fetuses with unossified sternebrae, and decreased mean fetal body weights. In a prenatal developmental toxicity study in rabbits, maternal (systemic) effects observed included mortality and clinical signs of toxicity at the HDT (350 mg/kg/day). In the rabbits, developmental toxicity was not observed at any dose. On the basis of developmental studies in rats and rabbits and reproductive findings in rats, glyphosate exhibited no evidence of increased susceptibility of offspring.

Neurotoxicity has not been observed in any of the acute, subchronic, chronic, developmental, or reproductive studies performed with glyphosate. New data requirements have been established under the revised 40 CFR Part 158 for registration of pesticides for food and non-food uses which include the requirement of an acute neurotoxicity study and a subchronic neurotoxicity study (Attachment 5). Similarly, 40 CFR Part 158 also requires an immunotoxicity study (Attachment 6).

The endpoints used for risk assessment purposes from the most recent human-health risk assessment (Memo, J. Tomerlin, 29-Sep-2006, D321992) can be found in Attachment 2.

The Food Quality Protection Act (FQPA) Safety Factor Committee (SFC) met on April 6, 1998 and addressed the potential enhanced sensitivity to infants and children as required by the FQPA (Memo, B. Tarplee, 17-Apr-98, TXR012584). The Committee recommended the 10x FQPA SF be reduced to 1x in assessing the risk posed by this chemical because: 1) there is no evidence of quantitative or qualitative increased susceptibility of the young demonstrated in the prenatal developmental studies in rats and rabbits and pre/post natal reproduction study in rats; 2) the toxicology database is adequate for FQPA assessment; 3) a developmental neurotoxicity study is not required and there was no evidence of neurotoxicity in any submitted study; and 4) the dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children.

AMPA

AMPA is a metabolite of glyphosate. In a 90-day oral toxicity study in rats, a LOAEL was identified for AMPA at 1200 mg/kg/day based on body weight loss and histopathological lesions of the urinary bladder. Previously the HED Metabolism Committee determined that, based on toxicological considerations, AMPA need not be regulated and should be dropped from the tolerance expression (Memo, R.B. Perfetti, 19-Aug-92). Furthermore, in a 17-Mar-94 meeting, the HED Metabolism Committee discussed whether uses that result in significantly higher residues of AMPA in plants and livestock commodities in the future would require that AMPA be reintroduced into the tolerance expression of glyphosate. The Committee determined that, based on toxicological considerations, AMPA need not be regulated regardless of levels observed in foods or feeds (Memo, R.B. Perfetti, 17-Mar-94).

N-Acetyl-Glyphosate

N-acetyl-glyphosate is a metabolite of glyphosate which is formed in certain transgenic crops. The acute oral LD₅₀ was greater than 5000 mg/kg in rats. Based on structural similarity with glyphosate, structure-activity relationships [(SAR); lack of structural alerts for carcinogenicity, mutagenicity, and endocrine effects], low acute toxicity, low subchronic toxicity, and lack of mutagenicity, N-acetyl-glyphosate is considered to be equally toxic as glyphosate.

N-Acetyl-AMPA

N-acetyl-AMPA is a minor metabolite of glyphosate which is formed in certain transgenic crops. *N*-acetyl-AMPA is expected to be of low acute toxicity and was negative for mutagenicity. It is not expected to be absorbed quickly from the gastrointestinal (GI) tract since it is a charged molecule at the physiological pH. Therefore, it is expected to be less toxic than *N*-acetyl-glyphosate. The metabolism study in rats with *N*-acetyl-glyphosate indicated that about 99% of the parent compound was isolated in the excreta. Based on this and the minimal plant residue concentrations, *N*-acetyl-AMPA was excluded as a residue of concern.

EPA is required under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency’s Endocrine Disruptor Screening Program (EDSP) have been developed and vetted, glyphosate may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Conclusions

As specified in the new 40 CFR Part 158 data requirements, immunotoxicity, acute neurotoxicity, and subchronic neurotoxicity studies should be conducted. The decision that AMPA need not be regulated, regardless of levels observed in foods or feeds, may be revisited during the registration review process.

Residue Chemistry

The qualitative nature of glyphosate residues in plants and livestock is adequately understood. Metabolism studies conducted with nontransgenic corn, cotton, soybeans, and wheat were previously submitted and reviewed. Based on these data, HED concluded that the residue of concern in/on nontransgenic plants is glyphosate *per se* (Memo, R. Perfetti, 19-Aug-1992; Memo, R. Perfetti, 27-Oct-1992, D183202; Memo, R. Perfetti, 17-Mar-1994). Metabolism studies have also been submitted on glyphosate-tolerant canola (Memo, T. Bloem, 30-Nov-1998, D242628) and glyphosate-tolerant corn (Memo, G. Kramer, 14-Mar-1996, D217539). The glyphosate-tolerant canola and corn were genetically modified to express the EPSPS gene derived from *Agrobacterium sp.* (strain CP4) which codes for an EPSPS protein that has reduced affinity for glyphosate as compared to the endogenous EPSPS protein. The glyphosate-tolerant canola and corn were also genetically engineered to express the oxireductase gene which converts glyphosate to the nonherbicidal AMPA. Metabolism in these varieties of transgenic canola and corn was essentially the same as the nontransgenic plants. Therefore, it was concluded that the terminal residue to be regulated in nontransgenic plants and transgenic corn

and canola modified to express the *Agrobacterium sp.* EPSPS and oxireductase genes is glyphosate *per se*.

Subsequent to this decision, DuPont submitted and HED approved a request permitting the commercialization of a new transgenic variety of soybean [Optimum™ GAT™ soybean (DP-356Ø43-5)]. The Optimum™ GAT™ soybean was engineered to express the microbial glyphosate acetyltransferase gene (*gat4601*), which confers tolerance to glyphosate via acetylation of the secondary amine group of glyphosate (results in formation of the nonherbicidal *N*-acetyl-glyphosate). As a result of the introduction of this seed line, HED concluded that the residues of concern in/on plants for tolerance expression and risk assessment should changed from glyphosate *per se* to the combined residues of glyphosate and *N*-acetyl-glyphosate (T. Bloem, 12-Mar-2008, D346713). Following this decision, it was determined that only the tolerance expression for soybeans would change from glyphosate *per se* to the combined residues of glyphosate and *N*-acetyl-glyphosate; the tolerance expression for all other crops would remain as glyphosate *per se*. Studies were then submitted by DuPont and reviewed by HED for Optimum™ GAT™ field corn, a transgenic variety of corn which expresses the microbial glyphosate acetyltransferase gene (*gat4601*). This submission resulted in a change to the tolerance expression for field corn from glyphosate *per se* to the combined residues of glyphosate and *N*-acetyl-glyphosate (Memo, T. Bloem, 29-Oct-08, D357880).

The residue chemistry database is sufficient to support the current registrations; however, there are some outstanding studies regarding the recent Optimum™ GAT™ soybeans and Optimum™ GAT™ field corn submissions which, if submitted, would change the registration status from conditional to unconditional (Memo, T. Bloem, 18-Mar-08, D345923; and Memo, T. Bloem, 29-Oct-08, D357880). The requested studies include nature of the residue studies in plants and livestock, and ruminant and poultry feeding studies. See the data requirements section for more information.

Conclusions

The qualitative nature of glyphosate residues in plants and livestock is adequately understood. The terminal residue to be regulated in nontransgenic plants and transgenic corn and canola modified to express the *Agrobacterium sp.* EPSPS and oxireductase genes is glyphosate *per se*. For crops (currently soybeans and corn) which have a transgenic variety that has been engineered to express the microbial glyphosate acetyltransferase gene (*gat4601*), the combined residues to be regulated are glyphosate and *N*-acetyl-glyphosate. The residue chemistry database is sufficient to support the current registrations; however, there are some outstanding studies which, if submitted, would change the registration status from conditional to unconditional.

Dietary Exposure

The most recent chronic dietary-exposure assessment was performed in conjunction with the September 2006 human-health risk assessment. No toxicological endpoint attributable to a single dose of glyphosate was identified by HED; therefore, an acute dietary-exposure assessment was not conducted. Glyphosate is classified as not likely to be a human carcinogen, so a cancer dietary-exposure analysis is not required. Chronic dietary risk assessments were conducted using DEEM™-FCID, ver. 2.03. DEEM™-FCID incorporates the food consumption

data from the United States Department of Agriculture's (USDA's) Continuing Surveys of Food Intakes by Individuals (CSFII; 1994-1996 and 1998).

The chronic analyses incorporated tolerance-level residues, 100% crop treated data for all commodities, and drinking water exposure estimates. The analysis used drinking water estimates from the direct application of glyphosate to water (230 ppb), which is the most conservative drinking water estimate. EFED has confirmed that the concentration estimate from the direct application of glyphosate to water is still the worst-case scenario estimate for the possible concentration of glyphosate in water.

Based on the 2006 analysis, the chronic exposure estimate of the U.S. population is 2% of the chronic population-adjusted dose (cPAD) and is, therefore, less than HED's level of concern (<100% of the cPAD). Infants <1 year old represent the most highly exposed population subgroup at 7% of the cPAD.

Conclusions

The dietary-exposure database is adequate to support the existing registrations. HED does not require a new chronic dietary risk assessment at this time because the most recent assessment incorporated concentration estimates from the direct application of glyphosate to water, and these estimates still represent the worst-case scenario. If any decisions regarding residues requiring regulation are made during the registration review process, a new dietary-exposure analysis may be required.

Residential Exposure

Glyphosate, a non-selective herbicide, is registered for broadcast and spot treatments on home lawns and gardens. Glyphosate products for homeowner use are packaged as ready-to-mix formulations and ready-to-use sprayers and are common in home and garden stores in the U.S. Glyphosate products are used by lawn care operators (LCOs) for broadcast and spot treatment weed control programs on homeowner lawns. Glyphosate products are also labeled for turf renovation.

Glyphosate is registered for use in recreational areas, including parks and golf courses for control of broadleaf weeds and grasses. Additional registered uses include applications to lakes and ponds, including reservoirs, for non-selective control of nuisance aquatic weeds.

Residential Handlers

Based on the registered residential use patterns, there is a potential for short-term dermal and inhalation exposures to homeowners who mix and apply products containing glyphosate (residential handlers). However, since short- and intermediate-term dermal or inhalation endpoints were not selected, no residential handler assessment is needed.

Residential Post Application

Post-application dermal and inhalation assessments are not needed since short- and intermediate-term dermal or inhalation endpoints were not selected. However, based on the registered use patterns, toddlers may have short-term post-application incidental oral exposures from hand-to-

mouth behavior on treated lawns and swimmers may to have short-term post-application incidental oral exposures from aquatic uses.

The Agency previously assessed post-application incidental oral ingestion exposure for toddlers in the most recent HED human-health risk assessment (Memo, J. Tomerlin, 29-Sep-2006, D321992). The standard operating procedures (SOPs) for Residential Exposure Assessments, Draft, 17-Dec-1997 and Exposure Science Advisory Committee (ExpoSAC) Policy No. 11, 22-Feb-2001: Recommended Revisions to the SOPs for Residential Exposure were used to estimate post-application incidental oral ingestion exposures and risk estimates for toddlers.

Also assessed were incidental oral exposures for adult, children, and toddler swimmers may have short-term post-application incidental ingestion exposures. The exposure assumptions used in the swimmer assessment are based on HED's Standard Operating Procedures for Residential Exposure Assessments, Draft, 17-Dec-1997 and subsequent updates for swimming pools adapted for this assessment, but the Residential SOP assumptions are considered conservative for use in assessing this scenario.

While adult and child golfers may have short-term post-application dermal exposure at golf courses, no dermal assessments were required because HED did not identify short- or intermediate-term dermal endpoints.

In the 2006 risk assessment, the MOEs for post-application toddler oral exposures were calculated using the highest application rate (1.62 lb ae/A) registered at the time of assessment. All of these MOEs were greater than 100 and did not exceed HED's level of concern for residential exposures (MOEs <100). In October of 2008, a new residential use product (Roundup® Weed & Grass Killer Super Concentrate; EPA Reg. No. 71995-25) was registered which has a higher application rate (10.5 lb ae/A). This new application rate is not expected to lead to residential exposures which exceed HED's level of concern (MOEs <100); however, a new residential exposure risk assessment is required.

MOEs for post-application exposure of swimmers to glyphosate after aquatic weed control applications are greater than 100 and do not exceed HED's level of concern for short-term non-occupational (recreational) exposures (MOEs <100). See Attachment 3 for a table which summarizes residential post-application use patterns and corresponding MOEs. Based on the new residential use product (EPA Reg. No. 71995-25) which has a higher rate of application (10.5 lb ae/A), the residential exposures and MOEs for toddlers presented in Attachment 3 will change; however the increased application rate is not expected to lead to exposures which exceed HED's level of concern for residential exposures (MOEs <100). These changes will be reflected in the new residential exposure risk assessment.

Conclusions

There is sufficient information available to assess residential exposure. A new residential exposure risk assessment is required due to the registration of a new residential-use product with an application rate which is higher than the rate previously assessed. The new application rate is not expected to lead to residential exposures which exceed HED's level of concern (MOEs <100).

Aggregate Risk Assessment

In the most recent HED human-health risk assessment (Memo, J. Tomerlin, 29-Sep-06, D321992), aggregate risk assessments were performed for short-, intermediate-term and chronic exposures. No toxicological endpoint attributable to a single dose of glyphosate has been identified by HED, so an acute aggregate risk analysis was not conducted. A cancer risk assessment was not conducted because there has been no evidence of carcinogenicity in any glyphosate toxicity study, and glyphosate has been classified as negative for carcinogenicity in humans.

In aggregating short- and intermediate-term risk, the Agency considered background chronic dietary exposure (food + water) and short- and intermediate-term incidental oral exposures. The Agency conducted the risk assessment using residential turf exposures estimates because the incidental oral ingestion exposure estimates for toddlers from residential turf exposures exceeded the estimates from post-application swimmer exposures and represented the worst-case scenario. Exposures from the swimmer and residential turf scenarios were not combined due to the low probability of both occurring.

In the 2006 risk assessment, dietary (food + water) exposures were combined with the estimated residential exposure and the combined exposure was then used to calculate an MOE for aggregate risk. The total short- and intermediate-term food and residential aggregate MOEs for children 1-2 years of age and adults 20-49 years old were 1400 and 4610, respectively. Since these MOEs are greater than 100, the short- and intermediate-term aggregate risk does not exceed HED's level of concern. The short- and intermediate-term aggregate risk section of the 2006 risk assessment identified children 1-2 years old as the most highly exposed population subgroup; however, the chronic dietary analysis identified all infants <1 year old as the most highly exposed population subgroup. This is not expected to change the MOE in such a way that it will exceed HED's level of concern.

Because no residential uses result in long-term exposure, the long-term aggregate risk did not include estimates of residential risk. Since water residues were incorporated into the chronic dietary risk assessment, the chronic dietary risk assessment also provides the estimate of long-term aggregate risk. The long-term aggregate risk does not exceed HED's level of concern.

A new aggregate risk assessment, which takes into account the new estimated residential exposures, will need to be conducted once the updated residential exposure risk assessment has been completed. The increase in the residential application rate, and subsequent change in estimated residential exposures, is not expected to affect the aggregate risk in such a way that it exceeds the Agency's level of concern.

Conclusions

The 2006 aggregate risk assessment found no risks of concern; however due to the registration of a product with a higher application rate than previously assessed, a new aggregate risk assessment will need to be conducted once the residential exposure risk assessment has been completed. The increase in the residential application rate, and subsequent change in estimated residential exposures, is not expected to affect the aggregate risk in such a way that it exceeds

HED's level of concern. If decisions regarding residues requiring regulation or new toxicological considerations are made during the registration review process, these decisions will be taken into account in the new aggregate exposure assessment.

Occupational Exposure

Glyphosate is a non-selective herbicide registered for use on a variety of fruit, vegetable, and field crops. Registered uses range from tree nuts, citrus, and grapes to corn, soybeans, cotton, and rice. Glyphosate is also registered for use on transgenic crop varieties such as canola, corn, cotton, soybeans, sugar beets, and wheat. Aquatic and terrestrial registered uses of glyphosate include non-selective control of nuisance aquatic weeds, ornamentals, greenhouses, residential areas, ornamental lawns and turf, fallow land, pastures, and nonagricultural rights-of-way. Glyphosate is formulated in liquid and solid forms, and it is applied using ground and aerial equipment.

Occupational Handlers

Based on the registered uses of glyphosate, commercial handlers and grower/applicators are expected to have short-term dermal and inhalation exposures. No handler assessment was required because no short-term dermal or inhalation endpoints were selected.

Occupational Post Application

Occupational post-application assessments are not required because no short-term dermal or inhalation endpoints were selected by HED. Exposures from occupational and/or residential uses of glyphosate are not expected to pose undue risks.

Conclusions

Since no short-term dermal or inhalation endpoints were identified, no occupational handler or occupational post-application assessments were required.

Public Health and Pesticide Epidemiology Data

A summary report listing incidents for glyphosate reported to the OPP Incident Data System (IDS) has been provided for the docket (Memo, M. Hawkins, 12-Mar-09). The report represents incidents occurring in the U.S. from 2002 to the present for glyphosate only. Since 2002, 289 incidents regarding glyphosate have been reported.

Human Incident Data: OPP IDS (2009)

The OPP IDS was consulted for poisoning incident data on the active ingredient glyphosate. The purpose of the database search was to identify potential patterns in the extent and severity of the health effects attributed to glyphosate exposure. The IDS includes reports of incidents from various sources, including mandatory Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 6 (a) (2) reports from registrants, other federal, state health, and environmental agencies, and individual consumers. The following databases were not searched for poisoning incident data: the American Association of Poison Control Centers Toxic Exposure Surveillance

System (TESS), the California Pesticide Illness Surveillance Program, and the National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR).

Reports of adverse health effects allegedly due to a specific pesticide exposure (an "incident") are largely self-reported and therefore, neither exposure to a pesticide nor reported symptom (or the connection between the two) is validated. However, incident information can be an important feedback loop to the Agency; incidents of severe outcome, or a suggested pattern or trend among less severe incidents can signal the Agency to further investigate a particular chemical or product.

FIFRA Section 6(a)(2) includes reports of alleged human health incidents from various sources, including mandatory reports from registrants, other federal, state health, and environmental agencies, and individual consumers. Since 1992, OPP has compiled these reports in an IDS. The majority of reports submitted to the IDS represent anecdotal reports or allegations only. Typically, OPP does not draw firm conclusions implicating the pesticide is causally associated with the reported health effects. Nevertheless, in some instances if enough cases and/or documentation of exposure and health effect or suggested patterns of exposure and response are indicative of a strong relationship, risk mitigation measures may be suggested.

The incident report identified that 289 case reports, which were allegedly attributable to glyphosate, were reported to the IDS between 2002 and 2008. The written content of each summarized case-report was reviewed to determine the health effects most commonly reported to be associated with glyphosate use/exposure. Eight major types of adverse health effects were identified through IDS: gastro-intestinal (4.8%), dermal (30.1%), upper-respiratory (10.3%), neurological (34.3%), cardiovascular (0.3%), ocular (13.8%), muscular (0.3%), and combination (5.5%) effects. Only 2 case reports (0.7%) alleged exposure with no symptoms reported. Disturbances of the gastrointestinal and neurological systems are congruent with classic organophosphate exposure within the GI system. Among the case reports, gastrointestinal effects reported included diarrhea, abdominal cramps, and stomach pain. Neurological system effects included shaking, loss of coordination, tingling, neuropathy, ataxia, and numbness. Dermal effects included blisters, rash, pruritus, skin irritation, hives, welts, sores, burning skin, and peeling skin. Many of the dermal cases were associated with splashing and/or leaking of the product onto the hands. Among the case reports, the majority of the reported symptoms involved dermal and neurological effects.

Glyphosate exhibits low toxicity via the oral, dermal, and inhalation routes (Toxicity Category III or IV). Glyphosate is a mild eye irritant, a slight dermal irritant, and is not a dermal sensitizer.

Table 1. Major Types of Health Effects Identified through the IDS Search.	
Symptoms	Frequency (%)
Dermal	87 (30.1)
Gastro-intestinal	13 (4.8)
Upper Respiratory	30 (10.3)
Neurological	99 (34.3)

Table 1. Major Types of Health Effects Identified through the IDS Search.	
Symptoms	Frequency (%)
Combination	16 (5.5)
Ocular	40 (13.8)
Muscular	1 (0.3)
Cardiovascular	1 (0.3)
No Symptoms	2 (0.7)
Total	100¹

¹Overall frequency does not total 100% due to rounding.

Agricultural Health Study

The Agricultural Health Study (AHS) is a prospective cohort study of licensed private and commercial pesticide applicators and their spouses recruited in Iowa and North Carolina. A total of 89,658 people are enrolled, and 57,311 of these participants are private or commercial pesticide applicators. Potential causes of cancer and other diseases among farmers, their families, and commercial pesticide applicators are explored through the study. The AHS began recruitment in 1993 and is currently in Phase III of the study. Additional information about the AHS can be found on the study website: <http://aghealth.nci.nih.gov/index.html>.

A number of publications regarding pesticide exposure have resulted from the AHS. In a study (De Roos *et al.*, 2005) which looked at the cancer incidence among glyphosate-exposed commercial and private pesticide applicators in the AHS, De Roos *et al.* evaluated the associations between glyphosate exposure and incidence of all cancers combined and 12 relatively common cancer subtypes. Among the enrolled AHS pesticide applicators, 41,035 (75.5%) reported having ever used glyphosate and more than 97% of those participants who had used glyphosate were men. De Roos *et al.* identified glyphosate exposure as: “a) ever personally mixed or applied products containing glyphosate; b) cumulative lifetime days of use, or ‘cumulative exposure days’ (years of use x days/year); and c) intensity-weighted cumulative exposure days (years of use x days/year x estimated intensity level)” (De Roos *et al.*, 2005). For the purpose of this study, the time period used to identify incident cancers was from the date of enrollment through 31-Dec-2001. To estimate the exposure-response relationship between glyphosate and incidence of cancer, Poisson regression analyses were used. No association was found between glyphosate exposure and all cancer incidence or most of the specific cancer subtypes which were evaluated by the study. However, the study did find, based on a small number of cases, a suggested association between multiple myeloma and glyphosate exposure. The researchers recommended for additional follow up on the suggested association as more multiple myeloma cases occur within the AHS cohort.

Conclusions

A summary report listing incidents for glyphosate reported to the OPP IDS has been provided for the docket (Memo, M. Hawkins, 12-Mar-09; no DP barcode). The report represents incidents occurring in the U.S. from 2002 to the present for glyphosate only. Since 2002, 289 incidents regarding glyphosate have been reported. Eight major types of adverse health effects were identified through IDS including gastro-intestinal, dermal, upper-respiratory, neurological, cardiovascular, ocular, muscular, and combination effects. The IDS query resulted in a moderately large number of case reports which warrants searching the following databases for

consistency and reproducibility of the poisoning incident data: TESS, the California Pesticide Illness Surveillance Program, and NIOSH SENSOR. The reported incidents from the TESS, California Pesticide Illness Surveillance Program, and NIOSH SENSOR databases will be screened in more detail during the development of the Final Work Plan for glyphosate.

A study using AHS data which looked at the cancer incidence among glyphosate-exposed pesticide applicators did not find an association between glyphosate exposure and cancer incidence overall or with most cancer subtypes. A suggested association between multiple myeloma and glyphosate exposure was identified; however, the number of multiple myeloma cases in the AHS cohort was small. As more cases occur, this association should be revisited.

Tolerance Assessment and International Harmonization

U.S. permanent tolerances (listed in 40 CFR 180.364) and MRLs are summarized in Table 6 (Attachment 4). The U.S., Mexico, and Codex residue definitions are harmonized. There are discrepancies between the Canadian residue definition and residue definitions of the U.S., Mexico, and Codex. Canada, Mexico, and Codex have established MRLs for residues of glyphosate in/on several raw agricultural and livestock commodities, but several MRLs are not harmonized with U.S. tolerances. Specific limits which do not appear to be harmonized include: animal feed, nongrass, group 18; banana; canola, seed; cattle, meat byproducts; corn, field, grain; cotton, undelinted seed; flax, seed; fruit, citrus, group 10; goat, meat byproducts; grain, cereal, forage, fodder and straw, group 16, except field corn, forage; grain, cereal, group 15 except field corn, popcorn, rice, sweet corn, and wild rice; grass, forage, fodder and hay, group 17; hog, meat byproducts; mustard, seed; pea, dry; poultry, meat; poultry, meat byproducts; sheep, meat byproducts; soybean, seed; sugarcane, molasses; sunflower, seed; and vegetable, legume, group 6 except soybean and dry pea. These discrepancies have been bolded in Table 6.

Additional Information on Status from other Regulatory Agencies

- The European Union reviewed glyphosate in 2002 and it was included in Annex 1.
- Glyphosate has been given a "low" priority for assessment in California, which means that there has been no activity on it so far, and it is not being considered among those of most concern for risk assessment. If an issue of concern arises, the priority status of glyphosate could change.
- The Pest Management Regulatory Agency (PMRA) is in the process of developing a schedule for the review of glyphosate.

Conclusions

The U.S., Mexico, and Codex residue definitions are harmonized. There are discrepancies between the Canadian residue definition and residue definitions of the U.S., Mexico, and Codex. For some raw agricultural and livestock commodities, the tolerances and MRLs for the U.S., Canada, Mexico, and Codex are harmonized; however there are a variety of commodities for which the tolerance and MRLs are not harmonized.

Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in the human-health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," (<http://www.hss.energy.gov/nuclearsafety/env/guidance/justice/eo12898.pdf>). The OPP typically considers the highest potential exposures from the legal use of a pesticide when conducting human-health risk assessments, including, but not limited to, people who obtain drinking water from sources near agricultural areas, the variability of diets within the U.S., and people who may be exposed when harvesting crops. Should these highest exposures indicate potential risks of concern, OPP further refines the risk assessments to ensure that the risk estimates are based on the best available information.

Cumulative

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to glyphosate and any other substances, and glyphosate does not appear to produce a toxic metabolite produced by other substances. Prior to a final Registration Review decision for glyphosate, the Agency will determine if there is any new information, such as new hazard or exposure data or information on changes to the use pattern, which would affect the cumulative risk assessment. Should the Agency determine that new information on glyphosate is available that could potentially impact the cumulative risk assessment and result in a risk of concern, the Agency will revisit the cumulative risk assessment.

Human Studies

No human studies have been used and relied upon for a regulatory decision on glyphosate.

Data Requirements

Toxicology

An immunotoxicity, acute neurotoxicity, and subchronic neurotoxicity studies, which are now required as part of revised 40 CFR Part 158, should be submitted for glyphosate to support registration review.

The following toxicology studies have been submitted are still in the process of being reviewed. Once the review has been completed, the study reviews need to be added to IHAD. The information presented in these studies will be taken into account for the final registration review of glyphosate.

- 47311001 Mackenzie, S.; Shen, A (2007) IN-MCX20: Subchronic Toxicity 90-Day Feeding Study in Rats. Project Number: DUPONT/19008, 16394, 1026. Unpublished study prepared by Dupont CropScience. 21 p.
- 47311004 Wagner, V.; Klug, M. (2007) IN-EY252: Bacterial Reverse Mutation Assay. Project Number: AB47BT/503/BTL, 17186, 28057. Unpublished study prepared by Bioreliance. 71 p.

Residue Chemistry

The following studies were requested (Memo, T. Bloem, 18-Mar-08, D345923; and Memo, T. Bloem, 29-Oct-08, D357880), and are still outstanding:

- Nature of the Residue - Plants: The petitioner is requested to submit the full Optimum™ GAT™ soybean metabolism study as specified in 860.1300.
- Nature of the Residue - Livestock: The petitioner is requested to submit the ruminant and poultry metabolism studies referenced in the livestock method validation study (MRID 47311011; dosed with ¹⁴C-*N*-acetyl-glyphosate).
- Meat, Milk, Poultry, and Eggs: The petitioner is requested to submit the ruminant and poultry feeding studies referenced in the livestock validation study (MRID 47311011; dosed with *N*-acetyl-glyphosate).

Occupational and Residential Exposure

No new occupational exposure or residential exposure data requirements have been identified for glyphosate to support registration review.

References

Table 2. Memoranda Relevant to Registration Review.			
Author	Barcode	Date	Title
The Agricultural Health Study			http://aghealth.nci.nih.gov/index.html
T. Bloem	D253421	25-Feb-99	PP#2F04886. Glyphosate in/on Glyphosate-Tolerant Sugar Beets. HED Risk Assessment.
T. Bloem	D349696	5-Mar-08	Glyphosate. Section 3 Registration for Application to Transgenic Soybean. Request for Petition Method Validation (PMV).
T. Bloem	D346713, D349700, D349729	12-Mar-08	Petition: 6F7146. Glyphosate-Isopropylammonium and Pyriproxyfen Sodium. Application to Glyphosate-Tolerant Soybeans. Summary of Analytical Chemistry and Residue Data.
T. Bloem	D348927; D348928	2-Sep-08	Glyphosate. Label Amendment to Permit Application of Glyphosate to Bayer's Glyphosate-Tolerant Cotton GHB614.
T. Bloem	D357880	29-Oct-08	Glyphosate and Pyriproxyfen Sodium. Amended Section 3 Registration to Permit the Rotation to Glyphosate-Tolerant Field Corn and Glyphosate-Tolerant Soybean Following

Table 2. Memoranda Relevant to Registration Review.			
Author	Barcode	Date	Title
			Application to Glyphosate-Tolerant Cotton and Revision of the Field Corn Tolerance Expression. Summary of Analytical Chemistry and Residue Data.
T. Bloem, PV Shah	D345923; D348895	18-March-2008	Petition: 6F7146. Glyphosate-Isopropylammonium and Pyriproxyfen Sodium. Human-Health Risk Assessment for Application to Glyphosate-Tolerant Soybean.
T. Bloem, Chemist	D357880	29-Oct-08	Glyphosate and Pyriproxyfen Sodium. Amended Section 3 Registration to Permit the Rotation to Glyphosate-Tolerant Field Corn and Glyphosate-Tolerant Soybean Following Application to Glyphosate-Tolerant Cotton and Revision of the Field Corn Tolerance Expression. Summary of Analytical Chemistry and Residue Data.
T. Bloem	D242628, D245591	30-Nov-98	PP# 2E04118 (formerly 2H05650) - Glyphosate residues in/on glyphosate tolerant canola seed and canola meal. Amendment of 24-August-1998.
A.J. De Roos, A. Blair, J.A. Rusiecki, J.A. Hoppin, M. Svec, M.Dosemeci, D.P. Sandler, M.C. Alavanja	N/A	Jan-05	Cancer Incidence among Glyphosate-Exposed Pesticide Applicators in the Agricultural Health Study. Environmental Health Perspectives 113:49-54.
W. Donovan, W. Dykstra, M. Christian,	D267588	17-Aug-00	PP#s 9F05096; 9F06007; 8F04973; 9E06003; and ID# 00ND0025. Glyphosate in/on Alfalfa Hay and Forage; Field Corn Forage; Stover and Straw of the Cereal Grains Crop Group; Numerous Minor Crops; and Flax in North Dakota. HED Risk Assessment.
W. Donovan	D280830	15-Feb-02	Chronic Dietary Exposure Assessment for the Risk Assessment of Glyphosate; PC codes 417300 & 103601; DP Barcode D280830; Case 292955; Submission S579658.
W. Donovan	D280830	15-Feb-02	Chronic Dietary Exposure Assessment for the Risk Assessment of Glyphosate; PC codes 417300 & 103601; DP Barcode D280830; Case 292955; Submission S579658.
W. Donovan, W. Dykstra, J.T. Swackhammer	D280831	20-Feb-02	PP#s 0F06130, 0F06195, and 0F06273. Glyphosate in/on Pasture and Rangeland Grasses, Roundup Ready® Wheat, and Nongrass Animal Feeds. Health Effects Division (HED) Risk Assessment. Barcode D280831. PC Codes 103601 & 417300. Case 292955. Submission S579658.
W. Dykstra, Z. Ghali	TXR 000897	30-Oct-91	Second Peer Review of Glyphosate.

Table 2. Memoranda Relevant to Registration Review.			
Author	Barcode	Date	Title
W. Dykstra, J. Rowland	TXR012586	20-Apr-98	Glyphosate- Report of the Hazard Identification Assessment Review Committee.
M. Hawkins	N/A	12-Mar-09	Updated Review of Glyphosate Incident Reports.
G.F. Kramer	D311356	19-May-05	Residues of Concern in Transgenic Glyphosate-Tolerant Crops. PC Code 103601. DP# 311356. Decision# 351808.
G.F. Kramer	D217539	14-Mar-96	PP# 5F04555. Glyphosate in or on Corn Forage. Evaluation of Residue Data and Analytical Methods. MRID#s 437127-01 & -02. Chemical 103601. Barcodes D217539 & D217541. CBTS#s 15913 & 15914.
R.B. Perfetti	N/A	17-Mar-94	Decision: The Metabolism Committee Meetings for Glyphosate Held on March 17, 1994.
R.B. Perfetti	N/A	11-Aug-92	Briefing: To Be Presented to the HED Metabolism Committee At The Meeting of August 19, 1992: Glyphosate Regulations and Codex Harmonization.
R.B. Perfetti	N/A	19-Aug-92	Decision: The Metabolism Committee Meetings for Glyphosate Held on August 19, 1992.
R.B. Perfetti	N/A	2-Mar-94	Briefing: To Be Presented to the HED Metabolism Committee At The Meeting of March 9, 1994: Glyphosate/AMPA Regulation.
R.B. Perfetti	D183202	27-Oct-92	Glyphosate: List A Reregistration Case No. 0718: Product and Residue Chemistry Chapters For the Reregistration Eligibility Document (RED). CBRS No. 10,665, DP Barcode No. D183202.
J.T. Swackhammer	D281503	13-Mar-02	Occupational (and Updated Non-Occupational and Residential) Exposure Risk Assessment for the Use of Glyphosate, Isopropylamine salt on Alfalfa, Clover and other Forage Legumes, Roundup Ready® Wheat and Corn, Grass forage, Fodder, and Hay. PC Code: 103601; DP Barcode: D281503.
J.T. Swackhammer	D281884	4-Apr-02	Amendment to HED Risk Assessment, Glyphosate in/on Pasture and Rangeland Grasses, Roundup Ready® Wheat, and Nongrass Animal Feeds, PC Codes 103601 & 417300. Case 292955. Submission S579658. Barcode D281884.
B. Tarplee, J. Rowland	TXR012584	17-Apr-98	Glyphosate – Report of the FQPA Safety Factor Committee.
J.R. Tomerlin	D321992	29-Sep-06	Glyphosate Human Health Risk Assessment for Proposed Use on Indian Mulberry and Amended Use on Pea, Dry. PC Code: 417300, Petition No: 5E6987, DP Num: 321992, Decision No. 360557.
J.R. Tomerlin	D321667	6-May-06	Glyphosate: Safflower and Sunflower; Summary of Analytical Chemistry and Residue Data. Petition Number 4E6878.

Table 2. Memoranda Relevant to Registration Review.			
Author	Barcode	Date	Title
J.R. Tomerlin	D321666	8-May-06	Glyphosate: Chronic Dietary Exposure Assessment for the Section 3 Registration Action.
J.R. Tomerlin	D314255, D327313	13-Jun-06	Glyphosate: Coffee; Summary of Analytical Chemistry and Residue Data. Request to Amend WeatherMAX® Label to Lower the PHI to One Day.
J.R. Tomerlin	D314476	5-Sep-06	Glyphosate Human Health Risk Assessment for Proposed Uses on Safflower and Sunflower. PC Code: 103601, Petition No: 4E6878, DP Num: 314476.
J. R. Tomerlin	D322410	26-Sep-06	Glyphosate. Petition for the Establishment of a Permanent Tolerance for Use on Indian Mulberry and Request to Amend Use on Dry Pea. Summary of Analytical Chemistry and Residue Data. PP#5E6987.
	EPA 738-R-93-014	XX-Sep-93	Reregistration Eligibility Decision (RED) Document: Glyphosate,

Attachments

Attachment 1: Chemical Identity Table

Attachment 3: Exposure Potential for Adult and Child Short-term Aggregate Risk Estimates

Attachment 4: International Residue Limit Status

Attachment 5: DCI Justification for Acute and Subchronic Neurotoxicity Studies

Attachment 6: DCI Justification for Immunotoxicity Studies

Attachment 7: DCI Justification for Immunotoxicity Studies

Attachment 1: Chemical Identity Table

Table 3. Chemical Identity of Glyphosate.	
Common Name	Glyphosate
Chemical Name	<i>N</i> -(phosphonomethyl)glycine
PC Codes	103601 – glyphosate isopropylamine salt 103603 – sodium glyphosate 103604 – glyphosate monoammonium salt 103605 – glyphosate ethanolamine salt 103607 – glyphosate diammonium salt 103608 – glyphosate dimethylammonium salt 103613 – potassium glyphosate 417300 – glyphosate; free acid
Chemical Abstracts No.	38641-94-0, 70393-85-0, 40465-66-5, ?, 69254-40-6, 34494-04-7, 70901-20-1, 1071-83-6
Registration Review Case No.	0178
Chemical Class	Phosphanoglycine herbicide
Chemical Structure	<chem>OC(=O)CNCP(=O)(O)O</chem>

Attachment 2: Glyphosate Endpoint Selection Tables

Table 4. Summary of Toxicological Doses and Endpoints for Glyphosate for Use in Human-health Risk Assessments ¹ .			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary, Females 13-49 and all segments of the general population	None	None	An acute dietary endpoint was not selected for the general population or females 13-50, since an appropriate endpoint attributable to a single exposure was not identified in the toxicology data base.
Chronic Dietary (all populations)	NOAEL= 175 mg/kg/day UF = 100 Chronic RfD = 1.75 mg/kg/day	FQPA SF = 1x cPAD = <u>cRfD</u> cPAD = 1.75 mg/kg/day	Developmental Toxicity Study - rabbit LOAEL = 350 mg/kg/day based on diarrhea, nasal discharge and death in maternal animals
Short-, and Intermediate-Term Incidental, Oral (Residential)	NOAEL = 175 mg/kg/day	LOC for MOE = 100	Developmental Toxicity Study - rabbit LOAEL = 350 mg/kg/day based on diarrhea, nasal discharge and death in maternal animals
Short-, Intermediate- and Long-Term Dermal (1 - 30 days, 1-6 months, 6 months-lifetime) (Occupational/Residential)	None	None	Based on the systemic NOAEL of 1,000 mg/kg/day in the 21 day dermal toxicity study in rabbits and the lack of concern for developmental and reproductive effects, the quantification of dermal risks is not required.
Short-, Intermediate- and Long-Term Inhalation (1-30 days, 1- 6 months, 6 months-lifetime) (Occupational/Residential)	None	None	Based on the systemic toxicity NOAEL of 0.36 mg/L (HDT) in the 28-day inhalation toxicity study in rats, and the physical characteristics of the technical (wetcake), the quantification of inhalation risks is not required.
Cancer (oral, dermal, inhalation)	Classification: Group E; no evidence of carcinogenicity; risk assessment not required.		

¹ UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no-observed adverse-effect level, LOAEL = lowest-observed adverse-effect level, PAD = population-adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, HDT = highest dose tested.

Attachment 3: Exposure Potential for Adult and Child Short-term Aggregate Risk Estimates

Table 5. Exposure Potential for Adult and Child Short-term Aggregate Risk Estimates ¹ .					
Exposure Scenario		Exposure (Dose) mg ai/kg bw/day	MOE	Combined Exposure (Dose) mg/kg/day ²	Combined MOE ³
Toddler – Treated Turf ⁴	Incidental oral hand-to-mouth post-application exposure from contacting treated turf	0.0242	7,230	0.03025	5,800
	Incidental oral post-application exposure from ingestion of treated soil	8.13×10^{-5}	$>10^6$		
	Incidental oral post-application exposure from object-to-mouth	0.00605	28,900		
Toddler – Swimmer	Incidental oral post-application exposure from contacting treated water	0.023	7,610	--	--
Adult – Swimmer	Incidental oral post-application exposure from contacting treated water	0.00493	35,500	--	--

¹ Source of information: Memo, J.R. Tomerlin, 29-Sep-06, D321992.

² Combined exposure (dose) (mg/kg/day) = Dose_{Hand-to-mouth} + Dose_{soil ingestion} + Dose_{Object-to-mouth}.

³ Combined MOE = NOAEL (175 mg/kg/day) / Combined exposure (dose) (mg/kg/day).

⁴ The residential exposures will change based on the new residential use product (EPA Reg. No. 71995-25) which higher rate of application (10.5 lb ae/A); however the increased application rate is not expected to lead to exposures which exceed HED's level of concern for residential exposures (MOEs <100). The new residential exposure risk assessment will reflect the change in rate of application.

Attachment 4: International Residue Limit Status

Table 6. Summary of U.S. Tolerances and International MRLs.				
U.S.		Canada	Mexico ¹	Codex
Residue Definition:				
40CFR180.364 glyphosate <i>N</i> -phosphonomethyl)glycine resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the dimethylamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate.		<i>N</i> - (phosphonomethyl) glycine, including the metabolite amino methylphosphonic acid (AMPA)	Glyphosate	#158 For compliance with MRLs in plant and animal commodities: Glyphosate.
Commodity Tolerance (ppm) /Maximum Residue Limit (mg/kg)				
Commodity	U.S.	Canada	Mexico	Codex
Acerola	0.2			
Alfalfa, seed	0.5			
Almond, hulls	25			
Aloe vera	0.5			
Ambarella	0.2			

Table 6. Summary of U.S. Tolerances and International MRLs.

U.S.		Canada	Mexico ¹	Codex
Animal feed, nongrass, group 18	400			Alfalfa fodder 500 Bean fodder 200 Pea hay or pea fodder (dry) 500
Artichoke, globe	0.2		0.2	
Asparagus	0.5	0.5		
Atemoya	0.2			
Avocado	0.2		0.2	
Bamboo, shoots	0.2			
Banana	0.2		0.2	0.05⁴
Barley, bran	30			
Beet, sugar, dried pulp	25			
Beet, sugar, roots	10	10		
Beet, sugar, tops	10			
Berry group 13	0.2			
Betelnut	1.0			
Biriba	0.2			
Blimbe	0.2			
Borage, seed	0.1			
Breadfruit	0.2			
Cacao bean	0.2		0.2	
Cactus, fruit	0.5			
Cactus, pads	0.5			
Canistel	0.2			
Canola, seed	20	10		Rape seed 20
Cattle, meat byproducts	5.0	Kidney 2 Liver 0.2		Edible offal (mammalian) 5
Chaya	1.0			
Cherimoya	0.2			
Citrus, dried pulp	1.5			
Coconut	0.1			
Coffee, bean	1.0		1	
Corn, field, forage	6.0			
Corn, field, grain	5.0	3	0.1	Maize 5
Corn, pop, grain	0.1			
Corn, sweet, grain	0.1			
Cotton, gin byproducts	175			
Cotton, undelinted seed	40		15	40
Cranberry	0.2			
Crambe, seed	0.1			
Custard apple	0.2			
Date	0.2			
Dokudami	2.0			
Durian	0.2			

Table 6. Summary of U.S. Tolerances and International MRLs.

U.S.		Canada	Mexico¹	Codex
Egg	0.05			0.05 ⁴
Epazote	1.3			
Feijoa	0.2			
Fig	0.2			
Fish	0.25			
Flax, meal	8.0			
Flax, seed	4.0	3		
Fruit, citrus, group 10	0.5		Lime 0.5 Lemon 0.2 Mandarin 0.5 Orange 0.2 Grapefruit 0.2 Tangerine 6	
Fruit, pome, group 11	0.2		Apple 0.2 Pear 0.2	
Fruit, stone, group 12	0.2		Apricot 0.2 Plum 0.2 Peach 0.2	
Galangal, roots	0.2			
Ginger, white, flower	0.2			
Goat, meat byproducts	5.0	Kidney 2 Liver 0.2		Edible offal (mammalian) 5
Gourd, buffalo, seed	0.1			
Governor's plum	0.2			
Gow kee, leaves	0.2			
Grain, aspirated fractions	100			
Grain, cereal, forage, fodder and straw, group 16, except field corn, forage	100			Barley straw and fodder (dry) 400 Oat straw and fodder (dry) 100 Sorghum straw and fodder (dry) 50 Wheat straw and fodder (dry) 300

Table 6. Summary of U.S. Tolerances and International MRLs.

U.S.		Canada	Mexico ¹	Codex
Grain, cereal, group 15 except field corn, popcorn, rice, sweet corn, and wild rice	30	Barley 10 Oats 15 Wheat 5	Rice 0.1 Oats 0.1 Barley 0.1 Rye 0.1 Sorghum 0.1 Wheat 5 Corn 0.1	Cereal grains 30 (except maize)
Maize fodder (dry)				150
Grape	0.2		0.2	
Grass, forage, fodder and hay, group 17	300		Alfalfa 200 Grass (pasture) 200	Hay or fodder of grasses (dry) 500
Guava	0.2		0.2	
Herbs subgroup 19A	0.2			
Hog, meat byproducts	5.0	Kidney 2 Liver 0.2		??Edible offal 0.5 ²
Hop, dried cones	7.0			
Horse, meat byproducts	5.0			Edible offal (mammalian) 5
Ilama	0.2			
Imbe	0.2			
Imbu	0.2			
Jaboticaba	0.2			
Jackfruit	0.2			
Jojoba, seed	0.1			
Juneberry	0.2			
Kava, roots	0.2			
Kenaf, forage	200			
Kiwifruit	0.2			
Lesquerella, seed	0.1			
Leucaena, forage	200			
Lingonberry	0.2			
Longan	0.2			
Lychee	0.2			
Mamey apple	0.2			
Mango	0.2		0.2	
Mangosteen	0.2			
Marmaladebox	0.2			
Meadowfoam, seed	0.1			
Mioga, flower	0.2			
Mustard, seed	0.1		0.2	

Table 6. Summary of U.S. Tolerances and International MRLs.

U.S.		Canada	Mexico¹	Codex
Noni	0.20			
Nut, pine	1.0			
Nut, tree, group 14	1.0		Walnut 1	
Okra	0.5			
Olive	0.2			
Oregano, Mexican, leaves	2.0			
Palm heart	0.2			
Palm heart, leaves	0.2			
Palm, oil	0.1			
Papaya	0.2		0.2	
Papaya, mountain	0.2			
Passionfruit	0.2			
Pawpaw	0.2			
Pea, dry³	8.0³	5.0 (dry?)	0.2 (dry?)	5
Peanut	0.1		0.1	
Peanut, hay	0.5			
Pepper leaf, fresh leaves	0.2			
Peppermint, tops	200			
Perilla, tops	1.8			
Persimmon	0.2			
Pineapple	0.1			
Pistachio	1.0			
Pomegranate	0.2			
Poultry, meat	0.1			0.05⁴
Poultry, meat byproducts	1.0	Kidney 2 Liver 0.2		Poultry edible offal 0.5
Pulasan	0.2			
Quinoa, grain	5.0			
Rambutan	0.2			
Rapeseed, seed	20			
Rice, grain	0.1		0.1	
Rice, wild, grain	0.1			
Rose apple	0.2			
Safflower, seed	85			
Salal	0.2			
Sapodilla	0.2			
Sapote, black	0.2			
Sapote, mamey	0.2			
Sapote, white	0.2			
Sesame, seed	0.1			
Sheep, meat byproducts	5.0	Kidney 2 Liver 0.2		Edible offal (mammalian) 5
Shellfish	3.0			
Soursop	0.2			
Soybean, forage	100			
Soybean, hay	200			
Soybean, hulls	100			

Table 6. Summary of U.S. Tolerances and International MRLs.				
U.S.		Canada	Mexico¹	Codex
Soybean, seed	20	20	6	20
Spanish lime	0.2			
Spearmint, tops	200			
Spice subgroup 19B	7.0			
Star apple	0.2			
Starfruit	0.2			
Stevia, dried leaves	1.0			
Strawberry	0.2			
Sugar apple	0.2			
Sugarcane, cane	2.0		2	2
Sugarcane, molasses	30			10
Sunflower, seed	85			7
Surinam cherry	0.2			
Tamarind	0.2			
Tea, dried	1.0			
Tea, instant	7.0			
Teff, grain	5.0			
Ti, leaves	0.2			
Ti, roots	0.2			
Ugli fruit	0.5			
Vegetable, bulb, group 3	0.2		Garlic 0.2 Onion 0.2	
Vegetable, cucurbit, group 9	0.5		Pumpkin 0.5 Watermelon 0.5 Cucumber 0.5 Melon 0.5	
Vegetable, foliage of legume, subgroup 7A, except soybean	0.2			
Vegetable, fruiting, group 8	0.1		Eggplant 0.1 Non-bell pepper 0.1 Tomato 0.1	
Vegetable, leafy, brassica, group 5	0.2		Broccoli 0.2 Cauliflower 0.2	

Table 6. Summary of U.S. Tolerances and International MRLs.

U.S.		Canada	Mexico ¹	Codex
Vegetable, leafy, except brassica, group 4	0.2		Spinach 0.2 Celery 0.2 Lettuce 0.2 Swiss chard 0.2	
Vegetable, leaves of root and tuber, group 2, except sugar beet tops	0.2			
Vegetable, legume, group 6 except soybean and dry pea	5.0	Beans 4.0 Lentils 4.0	Bean 0.2	Beans (dry) 2
Vegetable, root and tuber, group 1, except sugar beet	0.2		Carrot 0.2 Potato 0.2 Radish 0.2 Beet 0.2	
Wasabi, roots	0.2			
Water spinach, tops	0.2			
Watercress, upland	0.2			
Wax jambu	0.2			
Yacon, tuber	0.2			
Meat (from mammals other than marine mammals)				0.05 ⁴
Milks				0.05 ⁴
Wheat bran, unprocessed				20
Barley milling fractions, excluding flour		15		
Oats milling fractions, excluding flour		35		
Wheat milling fractions, except flour		15		
Chayote			0.5	

¹ As of 2004, latest date for available information. General practice is for Mexico to defer to US or Codex tolerances for its export purposes.

² Probable editorial error. No data to indicate derivation. Most likely is 5.

³ See legume vegetables.

⁴ Absent at the limit of quantitation.

Attachment 5: DCI Justification for Acute and Subchronic Neurotoxicity Studies**Guideline Number: 870.6200****Study Title: Acute and Subchronic Neurotoxicity****Rationale for Requiring the Data**

This is a data requirement under 40 CFR Part 158 as a part of the data requirements for registration of a pesticide (food and non-food uses).

The Neurotoxicity Test Guideline (OPPTS 870.6200) prescribes functional and structural neurotoxicity testing and is designed to evaluate the potential of a repeated chemical exposure to produce adverse effects on the nervous system. Although some information on neurotoxicity may be obtained from standard guideline toxicity study data, studies not specifically conducted to assess neurotoxic endpoints may be inadequate to characterize a pesticide's potential neurotoxicity. While data on clinical signs of toxicity or histopathology in routine chronic or subchronic toxicity studies may offer useful information on potential neurotoxic effects, these endpoints alone may be insufficient to detect more subtle neurological effects.

Practical Utility of the Data**How will the data be used?**

Neurotoxicity studies provide critical scientific information needed to characterize potential hazard to the human population on the nervous system from pesticide exposure. Since epidemiologic data on the effects of chemical exposures of glyphosate on neurologic parameters are nonexistent, animal studies are used as the most sensitive endpoint for risk assessment. These animal studies can be used to select endpoints and doses for use in risk assessment of all exposure scenarios and are considered a primary data source for reliable reference dose calculation.

How could the data impact the Agency's future decision-making?

If the neurotoxicity studies show that the test material poses either a greater or a diminished risk than that given in the interim decision's conclusion, the risk assessments for the test material may need to be revised to reflect the magnitude of potential risk derived from the new data.

If the Agency does not have this data, a 10X database uncertainty factor may be applied for conducting a risk assessment from the available studies.

Attachment 6: DCI Justification for Immunotoxicity Studies

Guideline Number: 870.7800 Study Title: Immunotoxicity
Rationale for Requiring the Data
<p>This is a new data requirement under 40 CFR Part 158 as a part of the data requirements for registration of a pesticide (food and non-food uses).</p> <p>The Immunotoxicity Test Guideline (OPPTS 870.7800) prescribes functional immunotoxicity testing and is designed to evaluate the potential of a repeated chemical exposure to produce adverse effects (i.e., suppression) on the immune system. Immunosuppression is a deficit in the ability of the immune system to respond to a challenge of bacterial or viral infections such as tuberculosis (TB), Severe Acquired Respiratory Syndrome (SARS), or neoplasia. Because the immune system is highly complex, studies not specifically conducted to assess immunotoxic endpoints are inadequate to characterize a pesticide's potential immunotoxicity. While data from hematology, lymphoid organ weights, and histopathology in routine chronic or subchronic toxicity studies may offer useful information on potential immunotoxic effects, these endpoints alone are insufficient to predict immunotoxicity.</p>
Practical Utility of the Data
<p>How will the data be used?</p> <p>Immunotoxicity studies provide critical scientific information needed to characterize potential hazard to the human population on the immune system from pesticide exposure. Since epidemiologic data on the effects of chemical exposures on immune parameters are limited and are inadequate to characterize a pesticide's potential immunotoxicity in humans, animal studies are used as the most sensitive endpoint for risk assessment. These animal studies can be used to select endpoints and doses for use in risk assessment of all exposure scenarios and are considered a primary data source for reliable reference dose calculation. For example, animal studies have demonstrated that immunotoxicity in rodents is one of the more sensitive manifestations of TCDD (2,3,7,8-tetrachlorodibenzo-p-dioxin) among developmental, reproductive, and endocrinologic toxicities. Additionally, the EPA has established an oral reference dose (RfD) for tributyltin oxide (TBTO) based on observed immunotoxicity in animal studies (IRIS, 1997).</p> <p>How could the data impact the Agency's future decision-making?</p> <p>If the immunotoxicity study shows that the test material poses either a greater or a diminished risk than that given in the interim decision's conclusion, the risk assessments for the test material may need to be revised to reflect the magnitude of potential risk derived from the new data.</p> <p>If the Agency does not have this data, a 10X database uncertainty factor may be applied for conducting a risk assessment from the available studies.</p>

Attachment 7: DCI Justification for Immunotoxicity Studies



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

March 12, 2009

MEMORANDUM

SUBJECT: Updated Review of Glyphosate Incident Reports

FROM: Monica Hawkins, M.P.H., Environmental Health Scientist
Toxicology and Epidemiology Branch
Health Effects Division (7509P)

Jessie Cordova, Information Technology Specialist
Toxicology and Epidemiology Branch
Health Effect Division (7509P)

THRU: Mary Manibusan, Branch Chief
Toxicology and Epidemiology Branch
Health Effects Division (7509P)

TO: John Pates, CRM
Special Review and Reregistration Division (7508P)

BACKGROUND

The OPP Incident Data System (IDS) was consulted for poisoning incident data on the active ingredient glyphosate. The purpose of the database search is to identify potential patterns on the extent and severity of the health effects attributed to glyphosate exposure. The IDS includes reports of incidents from various sources, including mandatory Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 6 (a) (2) reports from registrants, other federal and state health and environmental agencies and individual consumers. The following databases were not searched for poisoning incident data: the American Association of Poison Control Centers Toxic Exposure Surveillance System (TESS), the California Pesticide Illness Surveillance Program, and the National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR). The EPA is supplying the following incident report to fulfill our requirement to docket summaries of incident data that were reported

to the Agency. This report represents 289 incidents occurring in the United States from 2002 to the present for the single chemical only.

Reports of adverse health effects allegedly due to a specific pesticide exposure (an “incident”) is largely self-reported and therefore, generally speaking, neither exposure to a pesticide or reported symptom (or the connection between the two) is validated. However, incident information can be an important feedback loop to the Agency – incidents of severe outcome, or a suggested pattern or trend among less severe incidents can signal the Agency to further investigate a particular chemical or product.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 6(a)(2) includes reports of alleged human health incidents from various sources, including mandatory reports from registrants, other federal and state health and environmental agencies and individual consumers. Since 1992, OPP compiles these reports in an Incident Data System (IDS). Reports submitted to the IDS represent anecdotal reports or allegations only, unless otherwise stated in this report. Typically, OPP does not draw firm conclusions implicating the pesticide is causally associated with the reported health effects. Nevertheless, in some instances if enough cases and/or documentation of exposure and health effect or suggested patterns of exposure and response are indicative of a strong relationship, risk mitigation measures may be suggested.

In this evaluation, we identified 289 glyphosate case reports allegedly attributable to the organophosphate glyphosate reported to the IDS between 2002 and 2008. We reviewed the written content of each summarized case-report to determine the health effects most commonly allegedly associated with glyphosate use/exposure. Based on the IDS, we identified 8 major types of adverse health effects: gastro-intestinal (4.8%), dermal (30.1%), upper-respiratory (10.3%), neurological (34.3%), cardiovascular (0.3%), ocular (13.8%), muscular (0.3%), and combination (5.5%) effects. Only 2 case reports (0.7%) alleged exposure with no symptoms reported. Disturbances of the gastrointestinal and neurological systems are congruent with classic organophosphate exposure within the GI system. Among the case reports, gastrointestinal effects reported included diarrhea, abdominal cramps, stomach pain. Neurological system effects included shaking, loss of coordination, tingling, neuropathy, ataxia, and numbness. Dermal effects included blisters, rash, pruritus, skin irritation, hives, welts, sores, burning skin, and peeling skin. Many of the dermal cases are associated with splashing of the product that leaked onto hands. Among the case reports, the majority of the reported symptoms involved dermal and neurological effects.

Glyphosate exhibits low toxicity via the oral, dermal, and inhalation routes (Toxicity Category III or IV). Glyphosate exhibits only a mild eye irritation and slight dermal irritation and is not a skin irritant or sensitizer. In general, glyphosate is a moderately toxic insecticide and the IDS query resulted in a moderately large number of case reports which warrants searching the following databases for consistency and reproducibility of the poisoning incident data: the American Association of Poison Control Centers Toxic Exposure Surveillance System (TESS), the California Pesticide Illness Surveillance Program, and the National Institute of Occupational Safety and Health’s Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR).

Symptoms	Frequency (%)
Dermal	87 (30.1)
Gastro-intestinal	13 (4.8)
Upper Respiratory	30 (10.3)
Neurological	99 (34.3)
Combination	16 (5.5)
Ocular	40 (13.8)
Muscular	1 (0.3)
Cardiovascular	1 (0.3)
No Symptoms	2(0.7)
Total	100% ¹

¹overall frequency does not total 100% due to rounding.

IDS Report

3/12/09

Chemical: Glyphosate

103601

Human Incidents

Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
012676	001	21-Feb-02	ROUNDUP WEED & GRASS KILLER READY-TO-USE	07199500023		FL	HC	Man was pouring some of the product into his own sprayer and got some of the product on top of his hand. Unknown Adult (18-64 years old) Male reported Water Blisters and Redness.
012776	001	01-Mar-02	ROUNDUP WEED & GRASS KILLER CONCENTRATE	07199500026		CA	HC	Unknown Adult (18-64 years old) Female mixed the product with water and a small amount of the diluted product splashed into her eye. She reported Eye Redness, Irritation/Pain, and Superficial Corneal Abrasion.
012776	002	16-Mar-02	ROUNDUP WEED & GRASS KILLER READY-TO-USE	07199500023		VA	HC	Unknown Adult (18-64 years old) Male sprayed the product and the hose stretched away from the bottle and it broke off spraying him in the Face, Eye, and Nose. He reported Eye Irritation, Swollen, Redness, Difficulty Breathing, and Dizziness.
12852	002	09-Apr-02	ROUNDUP WEED & GRASS KILLER CONCENTRATE	07199500026		LA	HC	Unknown Adult (18-64 years old) Male used the diluted product while it was windy. Some of the product got into his eye or he rubbed his eye and scratched it. He reported Eye Irritation, Redness.
012852	003	17-Apr-02	ROUNDUP WEED & GRASS KILLER SUPER CONCENTRATE	07199500025		GA	HC	Unknown Adult (18-64 years old) Male got some of the diluted product in his eyes. He reported Irritation/Pain, Redness.

IDS Report

3/12/09

Chemical: Glyphosate

103601

Human Incidents

Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
012852	004	27-Apr-02	ROUNDUP WEED & GRASS KILLER CONCENTRATE	07199500026		NJ	HC	Unknown Adult (18-64 years old) Male sprayed the diluted product and the sprayer blew some of the product in his eyes and all over his body. He reported Ocular Irritation, Blurred Vision.
12854	001	17-Apr-02	KLEERAWAY GRASS & WEED KILLER 1 READY-TO-USE	07199500010	HARRISBURG	PA	HC	Unknown Adult (18-64 years old) Female reported Redness, Irritation after some of the product sprayed her in her eyes.
013090	001	15-Jun-02	GLYFOS X-TRA HERBICIDE	00478700023	SHEBOYGAN	WI	HC	Unknown Adult (18-64 years old) Female was possibly exposed during application of the product to farm crops. She reported Rash, Blisters from working in treated soil.
013105	001	13-Jun-02	ROUNDUP WEED & GRASS KILLER CONCENTRATE	07199500026		IN	HC	Unknown Adult (18-64 years old) Male sprayed a large area with the product and got a fair amount on his skin. On the same day the sprayer leaked on his left leg and soaked through his pants. He reported Rash, Redness, and Pruritus.
013105	002	18-Jun-02	ROUNDUP ULTRA MAX	00052400512		SC	HC	Unknown Adult (18-64 years old) Male sprayed the product with a spray gun when he tested the line. Some of the product sprayed into his eye. He reported Ocular Irritation, Redness.

IDS Report

3/12/09

Chemical: Glyphosate

103601

Human Incidents

Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
013181	001	08-Jul-02	ROUNDUP WEED AND GRASS KILLER READY TO USE FROM MONSANTO	07199500023		MI	HC	Unknown Adult (18-64 years old) Male, who has a landscaping business, got some of the product into his right eye. He was diagnosed with Corneal Abrasion.
013181	002	12-Jul-02	ROUNDUP WEED AND GRASS KILLER READY TO USE FROM MONSANTO	07199500008		WV	HC	Unknown Adult (18-64 years old) Female used the product. After she pulled on one of the pieces of equipment it flew in the air and hit her hand and caused an abrasion. She reported Skin Irritation.
013181	003	25-Jul-02	ROUNDUP WEED & GRASS KILLER SUPER CONCENTRATE FROM MONSANTO	07199500025		GA	HC	Unknown Adult (18-64 years old) Female mixed the product and some if it splashed into her eyes. She reported Burning Eyes.
013181	004	26-Jul-02	ROUNDUP WEED & GRASS KILLER CONCENTRATE FROM MONSANTO	07199500026		FL	HC	Unknown Adult (18-64 years old) Female used the product and some of it splashed into her eye. She reported Ocular Irritation, Redness.
013203	001	24-May-02	GLYFOS X-TRA	00478700023	YADKINVILLE	NC	HD	Unknown Adult (18-64 years old) Female reported Rash, Pruritus after some of the product blew into the air.
013223	001	17-Aug-02	PROSECUTOR	00022800366 010404			HB	Unknown Adult (18-64 years old) Male used a backpack sprayer to spray weeds in his backyard. Wore t-shirt & shorts, no shoes. Was later found passed out. No Symptoms Described.
013243	033	11-Jul-02	GROUND CLEAR COMPLEX VEGETATION KILLER (CONCENTRATE)	00023902657	MINNEAPOLIS	MN	HC	Unknown Adult (18-64 years old) Female reported Rash, Pruritus after using the product.

IDS Report

3/12/09

Chemical: Glyphosate

103601

Human Incidents

Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
013263	001	03-Aug-02	ROUNDUP W&G KILLER RTU	07199500023		ID	HC	A Man cleaned out a container and some of the product splashed into his right eye. Unknown Adult (18-64 years old) Male reported Irritation/Pain.
013263	002	07-Aug-02	ROUNDUP WEED & GRASS KILLER READY-TO-USE	07199500023		KS	HC	Unknown Adult (18-64 years old) Male reported Ocular Irritation, Dermal Irritation. He tried to open the container and it exploded in the man's Face, Eyes and Mouth.
013331	158	01-Aug-02	TRIOX LIQUID VEGETATION KILLER	00023902657	SAN FRANCISCO	CA	HC	Unknown Adult (18-64 years old) Female says that the neighbor sprayed the product and she can smell. No Symptoms Mentioned.
013386	003	18-Aug-02	GLYPRO (NAF-552)	06271900324	HELVETIA	WV	HC	A 72 year old Male reported Renal Failure, Dysphagia when the diluted product was sprayed near his farm.
013391	001	25-Sep-02	ROUNDUP WEED & GRASS KILLER	07199500025		MA	HC	Unknown Adult (18-64 years old) Female poured the product into a container to dilute it. Some of the product splashed directly into her eye. She reported Burning, Redness.
013391	002	28-Sep-02	ROUNDUP WEED & GRASS KILLER CONCENTRATE	07199500026		AL	HC	Unknown Adult (18-64 years old) Female. Some of the diluted product splashed into her left eye as she poured it into the container. She reported Irritation/Pain, Redness.

IDS Report

3/12/09

Chemical: Glyphosate

103601

Human Incidents

Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
013658	001	27-Dec-02	ROUNDUP ULTRA	00052400475		HI	HC	A wife sprayed the diluted product. Her husband walked behind her and was used a weed wacker on the area she had just sprayed. Unknown Adult (18-64 years old) Male reported Rash, Blisters, and Swelling.
013915	001	15-Jun-02	ROUNDUP W&G KILLER READY TO USE	07199500008	LA PALMA	CA	HC	Unknown Adult (18-64 years old) Male reported Nail Fungus. He used the product to kill weeds in his driveway. It took him over a half hour to complete the spraying and he noticed that the product had been coming out the trigger on the spray and dripping down his left hand.
014001	001	29-Apr-03	ROUNDUP W & G KILLER READY TO USE	07199500008		NC	HC	Unknown Adult (18-64 years old) Female employee experienced Blurred Vision & Burning Eyes after an accidental spraying near her eyes.
014039	001	09-Apr-03	GREEN THUMB CONCENTRATE WEED & GRASS KILLER	06776000059 009688	PRESCOTT	AZ	HC	Unknown Adult (18-64 years old) Female individual possibly exposed while applying product. The wind may have blown mist into the air while the product was being applied. She reported Dizziness, Weakness and Shaking.
014028	016	08-Apr-03	GROUND CLEAR SUPER EDGER PLUS KILLS PLUS PREVENTS WEEDS & GRASSES RTU	00023902516	PORTLAND	OR	HC	A 56 year old Male reported Tremor after some of the product splashed in his mouth while it was being applied.

IDS Report 3/12/09

Chemical: Glyphosate

103601

Human Incidents

Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
014028	021	08-Apr-03	GROUND CLEAR TRIOX TOTAL VEGETATION KILLER 1	00023902657	ROSEVILLE	CA	HC	A 40 year old Male reported Throat Irritation, Chest Pain, and Shortness of Breath after using the product 3 days earlier outside.
014068	001	29-May-03	KLEENUP PRO	00052400445 065783	OAKTON	MD	HC	A 23 year old Male reported Seizure after possible exposure to product.
014077	001	05-May-03	ROUNDUP WEED & GRASS KILLER SUPER CONCENTRATE	07199500025		CA	HC	Approximately 2 hours earlier, a man, who was at work, got some of the diluted product into his eye. Unknown Adult (18-64 years old) Male reported Eye Irritation, Redness, and Tearing.
014197	001	30-Jun-03	HONCHO		ANTELOPE	MT	HC	Unknown Adult (18-64 years old) Female reported a Skin Rash, Breathing Problems. She rode her bicycle and a County spray truck passed her. The truck did not stop spraying and as it went by her she was drenched.
014198	072	20-Jun-03	GROUND CLEAR COMPLETE VEGETATION KILLER (CONCENTRATE)	00023902657	AURORA	CO	HC	Unknown Adult (18-64 years old) Male reported Nausea, Lethargy and Cold Sores. He used the product for the past few weeks at work.
014198	075	24-Jun-03	GROUND CLEAR TRIOX TOTAL VEGETATION KILLER 1	00023902657	DELENA	MD	HC	Unknown Adult (18-64 years old) Male reported Tremor. Product was used within the last 2 hours by a maintenance man at an apartment building. The man spoke with the maintenance man while the product was being applied.

IDS Report

3/12/09

Chemical: Glyphosate

103601

Human Incidents

Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
014219	002	01-Jun-03	GLYFOS CONCENTRATE 41% WEED AND GRASS KILLER	06776000059009688	CRESTON	CA	HC	A 48 year old Female reported Nausea, Fever/Hyperthermia, Malaise while applying diluted product outdoors around residence area.
014313	001	21-Jun-03	NO-PEST WEED & GRASS KILLER CONCENTRATE	06776000046009688	GREENVILLE	NC	HC	A 31 year old Male used product and some got on his hands. Product remained on his skin for one hour. He reported Edema, Hives/Welts, and Shortness of Breath.
014335	001	11-Jul-03	ROUNDUP SUPER CONCENTRATE W & G KILLER1	07199500018		NJ	HC	Man sprayed the diluted product from a pressurized sprayer. The hose came undone and the product splashed in his eyes. Unknown Adult (18-64 years old) Male reported Eye Pain, Redness.
014335	002	20-Jul-03	ROUNDUP W & G KILLER READY-TO-USE	07199500023		NY	HC	Unknown Adult (18-64 years old) Female reported a seizure.
014335	003	22-Jul-03	ROUNDUP SUPER CONCENTRATE W & G KILLER1	07199500018		NC	HC	Unknown Adult (18-64 years old) Male sprayed the product in his yard once a week. He ran the mower over the yard and he states some of the ash from burning yard waste was in air. He reported Heavy Breathing and Growly Voice.
014335	004	27-Jul-03	ROUNDUP W & G KILLER SUPER CONCENTRATE	07199500025		NC	HC	A man applied the diluted product and some of it splashed in his eyes and on his face when he lost control of the sprayer. Unknown Adult (18-64 years old) Male

IDS Report

3/12/09

Chemical: Glyphosate

103601

Human Incidents

Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
								reported Eye Burning, Irritation/Pain.
014335	005	01-May-03	ROUNDUP W & G KILLER READY-TO-USE	07199500023		CA	HC	Unknown Adult (18-64 years old) Male used the product and reported with an Irregular Heartbeat and Palpitations.
014335	006	22-Jul-03	ROUNDUP W & G KILLER CONCENTRATE	07199500026		CO	HC	Unknown Adult (18-64 years old) Female reported Corneal Abrasion to the Eye. She cut weeds and something blew up into her eye after the product was applied to plants.
014335	007	28-Aug-03	ROUNDUP ULTRA	00052400475		PR	HC	Man used the diluted product and some of it spilled on his back and possibly splashed in his mouth. Unknown Adult (18-64 years old) Male reported Slurred Speech, Dizziness, Numb Tongue, and Loss of Coordination.
014370	001	27-Aug-03	ROUNDUP WEED & GRASS KILLER READY TO USE	07199500023		VA	HC	Unknown Adult (18-64 years old) Female reported Ocular Irritation after the product splashed into her eyes.
014317	084	29-Jul-03	KGRO GRASS & WEED KILLER 19READY-TO-USE)	07199500027 073327	WILLOW STREET	PA	HC	A 64 year old Female reported Shortness of Breath, Tachycardia after she applied the product yesterday.

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
014372	001	20-Aug-03	ROUNDUP WEED & GRASS KILLER READY-TO-USE	07199500023		VA	HC	A child reported Eye Irritation, Rash on Hand. The Product container was found open in a garage after the child came out of the garage.
014375	001	12-May-03	GLYFOS X-TRA HERBICIDE	00478700023	ELCO	GA	HC	A 36 year old Male reported Swelling, Edema, Chest Pain and Slurred Speech. The product may have splashed on his skin.
014375	002	18-Mar-03	GLYFOS X-TRA HERBICIDE	00478700023	SAN ANTONIO	TX	HC	A 79 year old Male reported Pain, Muscle Weakness, and Nighttime Swelling. Individual possibly exposed while applying product on a windy day.
014376	001	23-Aug-03	ROUNDUP CONCENTRATE WEED & GRASS KILLER	07199500017		NC	HC	Unknown Adult (18-64 years old) Male used the product and got some on his hands and then touched his eyes. He reported Blurred Vision.
014459	016	16-Sep-03	POWER FORCE GRASS & WEED KILLER 24 OZ RTU	06776000061 072155	STOW	OH	HC	The neighbor applied the product in his yard. He warned his neighbors that he was going to apply the product and should keep their dog and child indoors. A 6 year old Female reported Hives/Welts on her Face, Torso, Groin and Thighs.
014428	071	14-Aug-03	GROUND CLEAR COMPLETE VEGETATION KILLER (CONC)	00023902657	PARSONS	TN	HC	A 66 year Female mixed the product that splashed on her glasses and eyes. She reported Ocular Irritation/Pain, Blurred Vision.

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
014491	001	01-Jun-03	ROUNDUP WEED & GRASS KILLER1 READY-TO-USE	07199500023		MS	HC	Unknown Adult (18-64 years old) Female reported Numbness on Fingertips, Tingling after the product splashed on her hands.
014493	001	17-Oct-03	ROUNDUP HERBICIDE	00052400445		MI	HC	Unknown Adult (18-64 years old) Male carried a sack out of the store after purchasing the product that was leaking. Some of it splashed on his skin and on his stomach. He reported Rash, Blisters, Tingling and Itching.
014571	001	01-Oct-03	ROUNDUP GARDEN FOAM WEED & GRASS KILLER	07199500016		CO	HC	Unknown Adult (18-64 years old) Female used the product on weeds 4 weeks ago. Three days later she pulled the weeds. She reported Shortness of Breath, Fluid in her Lungs.
014576	001	01-Oct-03	ROUNDUP HERBICIDE	00052400445		OH	HC	Unknown Adult (18-64 years old) Female reported Rash, Red Bumps on her lower Legs. Sprayed unknown formulation of diluted product while she was wearing shorts, socks and shoes.
014578	001	01-Oct-03	ROUNDUP HERBICIDE	00052400445		ND	HC	Unknown Adult (18-64 years old) Male used the product to clear the weeds during the growing season. He reported Rash on Thumb and Middle Finger that began to spread.

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
014579	001	01-Oct-03	ROUNDUP HERBICIDE	00052400445		ID	HC	A neighbor sprayed the product on her own property and some of the product drifted over into their neighbor's yard. Unknown Adult (18-64 years old) Male was in the yard pulling grass and planting flowers. He reported Burning Sensation to his Hands, Blisters to the Shoulders, Chest, and all over his Body.
014580	001	01-Oct-03	ROUNDUP HERBICIDE	00052400445		MO	HC	The device to attach to the hose was faulty and the product sprayed all over his Legs. Unknown Adult (18-64 years old) Male reported Tingling, Neuropathy.
014673	001	01-Nov-03	ROUNDUP HERBICIDE	00052400445		VA	HC	A Pilot applied the diluted product from an airplane on a very hot day. Unknown Adult (18-64 years old) Male reported Seizure.
014674	001	01-Nov-03	ROUNDUP HERBICIDE	00052400445		TX	HC	Unknown Adult 18-64 years old) Male spilled the product on his truck. He reported Pneumonia, Blood Clots in his Lungs.
014720	001	01-Dec-03	ROUNDUP HERBICIDE	00052400445		FL	HC	Unknown Adult (18-64 years old) Female reported Diarrhea and Blood in Stool after the product was applied near her home.
014721	001	01-Mar-03	ROUNDUP HERBICIDE	00052400445		MD	HC	A Lawn service sprayed a man's patio for weeds that grew through the bricks. Unknown Adult (18-64 years old) Male reported Shortness of Breath, Panting and Pneumonia.

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
014931	001	01-Feb-04	ROUNDUP HERBICIDE	00052400445		TX	HC	A mother and her friend spraying the product. Unknown Adult (18-64 years old) Females reported Vomiting and Blood in Urine.
014962	013	20-Mar-04	POWER FORCE GRASS & WEED KILLER 1 GAL RTU	06776000061072155	MADDERY	LA	HC	A 41 year old Male used the product and got a small amount of the product in his eye. He reported Ocular Irritation/Pain.
014968	001	01-May-03	ROUNDUP HERBICIDE	00052400445		TN	HC	Unknown Adult (18-64 years old) Male reported Sores, Pruritus, and Rash. Some of the product spilled on his pants while he used it.
015007	001	19-Mar-04	ROUNDUP HERBICIDE	00052400445		FL	HC	Unknown Adult (18-64 years old) Male used the product for about an hour. He reported Chills, Nausea and Abdominal Cramping.
015111	001	01-Apr-04	ROUNDUP RTU W&G KILLER1	07199500023		CA	HC	Unknown Adult (18-64 years old) Male used the product about 2 weeks ago. He reported Shortness of Breath and was Diagnosed with Pneumonia.
015191	001	01-May-04	ROUNDUP HERBICIDE	00052400445		NV	HC	It was windy day and a tenant in the apartment building sprayed the product. Unknown Adult (18-64 years old) Female washed her hair with the window open and dried dirt landed on top of her wet head. She reported Itching, Chemical Burn, and Nausea.
015193	001	01-May-04	ROUNDUP W & G KILLER CONCENTRATE	07199500017		CA	HC	Unknown Adult (18-64 years old) Female reported Diarrhea. The woman cleaned a sprayer that was

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Human Incidents

Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
								used to spray the diluted product.
015195	001	01-May-04	ROUNDUP READY-TO-USE W&G KILLER1	07199500023		IN	HC	Unknown Adult (18-64 years old) Male released air from the sprayer bottle and some of the product splashed into his right eye. He reported Blurred Vision.
015197	001	06-May-04	ROUNDUP HERBICIDE	00052400445		GA	HC	Unknown Adult (18-64 years old) Male reported Fever, Body Aches, and Diarrhea. Some of the product may have splashed on his skin and also inhaled it.
015198	001	07-May-04	ROUNDUP ORIGINAL HERBICIDE FROM MONSANTO	00052400445		TN	HC	Unknown Adult (18-64 years old) Female sprayed the product three to four days ago. She did not use a mask on a windy day. She reported Coughing, Malaise.
015207	045	17-May-04	ORTHO BASIC SOLUTIONS WEED & GRASS KILLER CONCENTRATE	07199500006 000239	VALRICO	FL	HC	A 29 year old Male put some of the product into a sprayer and mixed it with water. When he was spraying he got some of the product on his thumb. He reported Dermal Irritation/Pain, Cold Sores.
015262	085	07-Jun-04	WEED & GRASS KILLER	07199500008	KANSAS CITY	KS	HC	Unknown Adult (18-64 years old) Male reported Rash, Skin Burning

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
015317	001	01-Jun-04	ROUNDUP ORIGINAL	00052400445		MD	HC	Unknown Adult (18-64 years old) Male purchased a product and he added one quart of the product to 12 gallons of water. He sat in the back of a truck spraying the product while his wife drove. He reported Pain in his Head, and Intermittent Burning all over his Body.
015319	001	11-Aug-04	ROUNDUP W&G KILLER CONCENTRATE	07199500017		NY	HC	Unknown Adult (18-64 years old) Male used a trigger sprayer for about one hour to apply the diluted product. He states he got a small amount of the product on his hands that had some abrasions on them. He reported Tremors in his Hands.
015320	001	01-Aug-04	ROUNDUP ORIGINAL	00052400445		HI	HC	Unknown Adult (18-64 years old) Female got product on her hands and later washed them. That evening she reported Difficulty Breathing, Burning and Itching.
015322	001	03-Jun-04	ROUNDUP ORIGINAL	00052400445		PA	HC	A 6 year old boy went to play at a neighbor's house. The Father states that the child's ball went into the weeds where the product was recently applied. The boy reported Stomach Pain.
015324	001	28-Jun-04	ROUNDUP BRUSHKILLER CONCENTRATE	07199500017		AZ	HC	Unknown Adult (18-64 years old) Male sprayed the diluted product with the appropriate amount of water as listed on the label. He reported Back Pain and Blood in the Urine.

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
015321	001	25-Jun-04	ROUNDUP HERBICIDE	00052400445	HAWAII	HI	HC	Unknown Adult (18-64 years old) Male sprayed the product. The sprayer leaked on both hands 1-2 times. He reported Numbness, Swelling and Itching in Both Hands.
015372	001	12-Jul-04	CLEAROUT 41 PLUS	07082900003	WESTERN PENNSYLVANIA	PA	HC	A 16 year old Female reported working a near table where the product was spilled. She reported Inhalation, Dizziness, Shortness of Breath, Numbness, and Asthma.
015419	066	05-Jul-04	SEASON-LONG GRASS & WEED KILLER 1 GAL READY-TO-USE	00023902516	ROCKVILLE	MD	HC	Unknown Adult (18-64 years old) Female reported Headache, Nausea, 5 hours after using the product.
015495	001	01-Jul-04	ROUNDUP	00052400445		WI	HC	Someone sprayed her lawn with the product as a malicious act. A child was playing in the grass later after it was dry. One week later, a Child (3-8 years old) Reported Blue Fingertips, Lips and a Fever.
015497	001	01-Jul-04	ROUNDUP ORIGINAL HERBICIDE	00052400445		CA	HC	Unknown Adult (18-64 years old) Female spilled a bottle in the back of her car. She rinsed the seats off with a hose and then squeezed the water out of the sham with her hands. She reported Numb Fingertips.
015498	001	01-Jul-04	ROUNDUP W & G KILLER READY TO USE	07199500023		OH	HC	Unknown Adult (18-64 years old) Male sprayed some weeds along his driveway with the product. The wind blew some of the product back on his Leg. He reported Blisters on Legs.

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
015499	001	01-Jul-04	ROUNDUP	00052400445		LA	HC	Unknown Adult (18-64 years old) Male sprayed the product and the hose came loose. Some of the product got on his hands. He reported Blisters, Swelling, Pain.
015501	001	01-Jul-04	ROUNDUP RTU W & G KILLER1	07199500023		NY	HC	Unknown Adult (18-64 years old) Male sprayed the formulation product. He reported Dermal Irritation/Pain.
015502	001	01-Jul-04	ROUNDUP RTU POISON IVY & TOUGH BRUSH KILLER	07199500032		OH	HC	A man reported Back Pain, Throat Pain, and Chest Pain after he applied the product on a windy day.
015505	001	01-Jul-04	ROUNDUP WEED & GRASS KILLER READY-TO-USE	07199500023		NC	HC	Unknown Adult (18-64 years old) Female reported Fluid-filled Blisters on Legs, Rash after the product was spilled.
015483	071	29-Aug-04	BASIC SOLUTIONS WEED AND GRASS KILLER	07199500027 000239	COLORADO SPRINGS	CO	HC	A 11 year old Child reported Hives/Welts all over her body while her mother treated their lawn with the product.
015483	079	16-Aug-04	GROUND CLEAR COMPLETE VEGETATION KILLER CONCENTRATE	00023902657	IRVING	TX	HC	Unknown Adult (18-64 years old) Male reported Hives, Itchy Rash, and Swollen Lower Lip.
015535	001	18-Aug-04	ROUNDUP WEED & GRASS KILLER CONCENTRATE	07199500017		TX	HC	Unknown Adult (18-64 years old) Male used the product off and on for six years. He applied the product on a windy day and reported Shortness of Breath.
015541	001	01-Aug-04	ROUNDUP W & G KILLER SUPER CONCENTRATE	07199500018		CA	HC	Unknown Adult (18-64 years old) Male used the product about 2 weeks ago. He reported Swollen Eyes.

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
015544	001	01-Aug-04	ROUNDUP HERBICIDE	00052400445		MI	HC	Unknown Adult (18-64 years old) Female applied the product using a pressure sprayer. The hose came loose and the left side of her Face and Body was splashed with the product. She reported Coughing, Bronchitis.
015545	001	01-Aug-04	ROUNDUP HERBICIDE	00052400445		FL	HC	Unknown Adult (18-64 years old) Female used the diluted product about one month ago. She opened the sprayer and no liquid was released, but is concerned with the air that was released from the sprayer. She reported Congestion later that evening. She was Diagnosed with Chronic Sinusitis.
015561	001	09-Sep-04	ROUNDUP PRO	00052400445		OR	HC	Unknown Adult (18-64 years old) Male used the product about one month ago. He may have splashed himself in the face with a drop of the product. He reported Edema, Fever, and Salivary Gland Swelling.
015562	001	27-Sep-04	ROUNDUP ORIGINAL HERBICIDE	00052400445		TX	HC	Unknown Adult (18-64 years old) Male sprayed the diluted product from his tractor. He reported Joint Pain.
015563	001	09-Sep-04	ROUNDUP WEED & GRASS KILLER CONCENTRATE	07199500026		NY	HC	Unknown Adult (18-64 years old) Male pulled some weeds in the garden where his wife sprayed the product the previous day. He reported Red Itchy Rash, Blisters

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
015565	001	13-Sep-04	ROUNDUP WEED & GRASS KILLER SUPER CONCENTRATE	07199500025		HI	HC	Unknown Adult (18-64 years old) Male sprayed the diluted product 10 days ago when it was windy. He reported Fatigue, Loss of Appetite.
015567	001	01-Sep-04	ROUNDUP READY TO USE W & G KILLER	07199500008		KS	HC	Unknown Adult (18-64 years old) Male used diluted product and got a small amount on his hands. He reported Tiny Lesions on his Hands, Swollen Fingers.
015568	001	09-Jan-04	ROUNDUP POISON IVY AND TOUGH BRUSH KILLER2 READY TO USE	07199500032		AL	HC	Unknown Adult (18-64 years old) Female sprayed the diluted product. She reported Coughing/Choking, Bronchitis
015569	001	01-Sep-04	ROUNDUP POISON IVY AND TOUGH BRUSH KILLER2 READY TO USE	07199500032		AL	HC	Unknown Adult (18-64 years old) Female mowed the grass and afterward she sprayed it with the diluted product. She wore shorts and reported Red and Swollen Skin, Blisters, Irritation/Pain.
015602	055	29-Sep-04	GROUND CLEAR COMPLETE VEGETATION KILLER CONCENTRATE	00023902657	CANAL FULTON	OH	HC	Unknown Adult (18-64 years old) Male used product 10 days ago when it was windy. Some of the product blew in his face that he wiped with his hands. He reported Blisters on Face.
015724	001	01-Oct-04	BUCCANEER	00052400445		MT	HC	Unknown Adult (18-64 years old) Male sprayed product. He pulled weeds that pierced his finger leaving a long cut. He reported Redness and Swollen Hand, Wrist.

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
015766	001	11-Oct-04	ROUNDUP WEED AND GRASS KILLER READY TO USE	07199500032		CA	HC	Unknown Adult (18-64 years old) Female reported sprayed the product and got some on her hands. She rubbed her eyes and reported Ocular Irritation/Pain.
015792	001	01-Nov-04	ROUNDUP CONCENTRATE WEED & GRASS KILLER	07199500017		FL	HC	Unknown Adult (18-64 years old) Male used the diluted product. He wore shorts during the application and thinks he might have gotten some of the mist of the product on his legs. He reported Redness of Skin, Irritation, and Blisters.
015718	001	01-Oct-04	ROUNDUP READY TO USE WEED & GRASS KILLER	07199500026		FL	HC	Unknown Adult (18-64 years old) Male mixed the product and some of it got on his fingers. He rinsed his hands with water, but he may have rubbed his eyelids with his hand. He reported Swollen Face, Itchy Eyelids.
015784	009	15-Sep-04	ORTHO BASIC SOLUTIONS WEED & GRASS KILLER CONCENTRATE	07199500006 000239	PORTLAND	OR	HC	A 45 year old Male reported Rash, Pruritus after he sprayed the product that splashed on his hands.
015823	001	04-Dec-04	ROUNDUP READY TO USE WEED AND GRASS KILLER	07199500008		AZ	HC	The nozzle on the sprayer dripped some of the product on a man's hands. An Unknown Adult (18-64 years old) Male reported Blisters.
015903	004	17-Nov-04	BASIC SOLUTIONS WEED AND GRASS KILLER	07199500027 000239	HOMESTEAD	FL	HC	A 66 year old Male applied product and reported Skin Peeling.

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
015976	001	01-Jan-05	ROUNDUP READY TO USE POISON IVY & TOUGH BRUSH KILLER	07199500032		AZ	HC	Unknown Adult (18-64 years old) Male used the diluted product and did not wear any type of protective clothing at the time. Some of the product may have gotten some onto his skin. He reported Slurred Speech, Muscle Incoordination, Diarrhea, and Difficulty Concentrating.
015987	001	06-Jan-04	ROUNDUP WEED & GRASS KILLER READY-TO-USE	07199500023		NC	HC	Unknown Adult (18-64 years old) Female treated crabgrass with the product on a windy day. She reported Ocular Irritation, Rash.
015974	007	22-Jan-05	BASIC SOLUTIONS WEED AND GRASS KILLER	07199500027 000239		TX	HC	Unknown Adult (18-64 years old) Female touched the neck of the product bottle and later rubbed the corner of her Eye. She reported Bloody Spot on Sclera.
016117	002	01-Mar-05	ROUNDUP HERBICIDE	00052400445		CA	HC	Unknown Adult (18-64 years old) Female sprayed the product and reported Slurred Speech.
016117	004	01-Mar-05	ROUNDUP WEED & GRASS KILLER CONCENTRATE	07199500026		SC	HC	Unknown Adult (18-64 years old) Male reported Rash after some of the product spilled on his hand.
016117	005	01-Mar-05	ROUNDUP CONCENTRATE WEED & GRASS KILLER	07199500017		CA	HC	A man applied the product with a pump that was under pressure. Some of the product splashed into his eyes and on his Face. Unknown Adult (18-64 years old) Male reported Eye Irritation, Redness.

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Incident Number		Incident Date	Product Name	Registration Number	City	State	Exposure Type*	Incident Description
016117	006	01-Mar-05	ROUNDUP CONCENTRATE WEED & GRASS KILLER	07199500017		FL	HC	The woman initially had shoes on when the product was sprayed on the grass. She ran back and forth into and out of her house. Unknown Adult (18-64 years old) Female reported Burning Sensation, Lesions on her Feet, Pain.
016126	012	12-Mar-05	ORTHO BASIC SOLUTIONS WEED & GRASS KILLER CONCENTRATE	07199500006 000239		AZ	HC	A 52 year old Female reported a Chest Pain after she applied the product for about 5 hours.
016218	001	19-Apr-05	ROUNDUP WEED & GRASS KILLER1 SUPER CONCENTRATE	07199500018		CA	HC	Unknown Adult (18-64 years old) Male got some of the product on his hands as the bottle was leaking. He reported Peeling Hands, Burning Sensation On Skin, and Low Platelet Count.
016218	004	01-Apr-05	ROUNDUP WEED & GRASS KILLER SUPER CONCENTRATE	07199500025		MO	HC	Unknown Adult (18-64 years old) Male diluted product and sprayed dandelions for four hours. He reported Chest Pain, Nausea, Chills, and Diarrhea.
016218	005	01-Apr-05	ROUNDUP ULTRAMAX	00052400512		TN	HC	Unknown Adult (18-64 years old) Female reported Ocular Irritation/Pain, Redness, and Corneal Abrasions. She was at the golf course while they sprayed the product with a sprayer for weeds. The person carrying the sprayer accidentally triggered the spray directly into the woman's Face, Eyes, and on her Skin